No. 01-188-CFX Title: Pharmaceutical Research and Manufacturers of America, Petitioner
v.
Kevin Concannon, Commissioner, Maine Department of Human Services, et al.

Docketed:
July 31, 2001

Court: United States Court of Appeals for the First Circuit

Entry	Date	Proceedings and Orders
	Jul 31 2001	Petition for writ of certiorari filed. (Response due August 30, 2001)
	Aug 29 2001	Brief of respondents Kevin Concannon, et al. in opposition filed.
	Aug 30 2001	Brief amici curiae of Washington Legal Foundation, et al. filed.
	Aug 30 2001	Brief amicus curiae of Chamber of Commerce of the United States filed.
	Sep 12 2001	DISTRIBUTED for Conference of October 5, 2001
	Sep 12 2001	Reply brief of petitioner Pharmaceutical Research & Manufacturers of America filed.
	Oct 9 2001	The Solicitor General is invited to file a brief in this case expressing the views of the United States.
	May 31 2002	Brief amicus curiae of United States filed.
	Jun 10 2002	Supplemental brief of petitioner filed.
	Jun 11 2002	REDISTRIBUTED for Conference of June 27, 2002
	Jun 28 2002	Petition GRANTED. SET FOR ARGUMENT January 22, 2003. **********
	Jul 19 2002	Order extending time to file the joint appendix and petitioner's brief on the merits to and including Septmeber 20, 2002.
	Sep 19 2002	Brief amicus curiae of Pacific Legal Foundation filed.
	Sep 20 2002	Brief of petitioner Pharmaceutical Research & Manufacturers of America filed.
	Sep 20 2002	LODGING consisting of twenty bound copies of related material received from counsel for the petitioner.
	Sep 20 2002	Brief amici curiae of International Patient Advocacy Association, et al. filed.
	Sep 20 2002	Brief amicus curiae of Chamber of Commerce of the United States of America filed.
	Sep 20 2002	Brief amici curiae of Washington Legal Foundation, et al. filed.
	Sep 20 2002	Brief amicus curiae of Long Term Care Pharmacy Alliance filed.
	Sep 20 2002	Brief amicus curiae of United States filed.
	Sep 20 2002	Brief amici curiae of Legal Services Orgs. Representing Medicaid Beneficiaries filed.
	Sep 20 2002	Joint appendix filed.
	Sep 20 2002	LODGING,consisting of twenty copies of "Report on Prescription Access Hot-Line",received from counsel for amicus Legal Services.
	Sep 25 2002	Order extending time to file respondent's brief on the merits to and including November 6, 2002.

No. 01-188-CFX

Entry	Date	Proceedings and Orders
	Nov 6 2002	Brief of respondents Kevin Concannon, et al. filed.
	Nov 6 2002	Brief amici curiae of National Conference of State Legislatures, et al. filed.
	Nov 6 2002	Brief amici curiae of AARP, et al. filed.
	Nov 6 2002	Brief amici curiae of Massachusetts, et al. filed.
	Nov 6 2002	Brief amici curiae of Maine Council of Senior Citizens, et al. filed.
	Nov 8 2002	LODGING consisting of twenty bound copies of related material received from counsel for amici Maine Council of Senior Citizens, et al.
	Nov 21 2002	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
	Dec 2 2002	Record filed.
	Dec 6 2002	Reply brief of petitioner Pharmaceutical Research & Manufacturers of America filed.
	Dec 7 2002	CIRCULATED.
	Dec 11 2002	Record filed.
	Dec 16 2002	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED.
	Jan 10 2003	Letter and attachment received from the Solicitor General and distributed.
	Jan 22 2003	ARGUED.

Supreme Court, U.S.
FILED

No. 01 188 JUL 31 2001

OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. § 1396 *et seq*., allows a state to use authority under that statute to compel drug manufacturers to subsidize price discounts on prescription drugs for non-Medicaid populations?

2. Whether a state may circumvent the Commerce Clause prohibition against regulating or taxing wholly out-of-state transactions by requiring an out-of-state manufacturer, which sells its products to wholesalers outside the state, to pay the state each time one of its products is subsequently sold by a retailer within the state?

PARTIES TO THE PROCEEDING

The Petitioner is the Pharmaceutical Research and Manufacturers of America ("PhRMA"). The Respondents are Kevin Concannon, the Commissioner of the Department of Human Services of the State of Maine, and G. Steven Rowe, the Attorney General of the State of Maine.

Petitioner PhRMA is a not-for-profit incorporated membership organization. There are no parent corporations or publicly held companies that own 10% or more of PhRMA's stock. A list of PhRMA's members may be found at http://www.phrma.org/who/memlist.phtml.

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OPINIONS BELOW

The opinion of the court of appeals (App. 1-53) is reported at 249 F.3d 66 (1st Cir. 2001). The order of the court of appeals declining to act on PhRMA's petition for rehearing *en banc* (App. 54-56) is unreported. The opinion of the district court (App. 57-72) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 16, 2001. On June 13, 2001 the court of appeals entered an order denying rehearing and declining action on PhRMA's timely petition for rehearing *en banc*. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. Article I, § 8, cl. 3 of the Constitution providing that "The Congress shall have Power...to regulate Commerce...among the several States...".

2. Article VI of the Constitution providing that "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof...shall be the supreme Law of the Land...".

3. Section 1927 of the Social Security Act, 42 U.S.C. § 1396r-8, governing the Medicaid prescription drug rebate program (App. 73-84).

4. The Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599), providing for the establishment and operation of a "Maine Rx" program to subsidize retail drug purchases (App. 85-108).

STATEMENT OF THE CASE

Maine seeks to compel out-of-state drug manufacturers, who sell their drugs to wholesalers outside Maine, to subsidize retail price discounts for Maine residents who purchase drugs in Maine. The First Circuit held that exacting such a subsidy does not violate the dormant Commerce Clause's prohibition on extraterritorial regulation by the states.

Maine seeks to enforce payment of this subsidy by using authority granted under the federal Medicaid statute, even though the new Maine subsidy program is wholly unrelated to Medicaid. Maine proposes to do so by limiting *Medicaid* patients' access to the drugs of manufacturers who do not submit to Maine's mandated subsidies for *non*-Medicaid patients under the new state program. The First Circuit held that Maine may use its authority under the federal Medicaid statute to compel such subsidies, while the D.C. Circuit has held that the Medicaid statute does not empower the governing federal agency to authorize states to use the Medicaid statute as leverage to extend Medicaid discounts to non-Medicaid populations.

Review by this Court is warranted to correct the First Circuit's erroneous reading of the limits to which the Medicaid statute may be stretched, and to resolve the conflict between the First Circuit and the D.C. Circuit over that important federal statutory question. Review is also warranted to clarify that states may not evade the Commerce Clause's prohibition against regulating wholly out-of-state sales transactions by demanding payments on goods sold out-of-state that are then resold by third parties inside the state. Both issues are of national importance. As the decision below (from Maine) and the decision in the D.C. Circuit case (from Vermont) illustrate, the harmful phenomenon of state efforts to use Medicaid leverage to exact non-Medicaid subsidies is fast spreading, with more

than two dozen states poised to enact laws similar to Maine's. Thus, this Court's resolution of the questions presented by this petition is urgently needed.

I. The Maine Rx Program

1. Declaring that the prices charged by drug manufacturers for their products are "excessive," Maine's Act to Establish Fairer Pricing for Prescription Drugs (the "Act"), 22 Me. Rev. Stat. Ann. § 2681 *et seq*. (App. 85-108), requires drug manufacturers to subsidize retail price discounts to Maine residents under a new state program called "Maine Rx." The Act requires all drug manufacturers whose products are ultimately sold in Maine to enter into "rebate agreements" with the state, and to make payments to subsidize such discounts—regardless of whether the manufacturers actually sell the drugs in Maine. 22 Me. Rev. Stat. Ann. § 2681(3).

Under these agreements, a manufacturer must make a "rebate" payment to the State for each unit of a drug that is sold by a Maine pharmacy to a participating Maine resident. The Act requires a manufacturer to make such payments even if the manufacturer is a complete stranger to that in-state sales transaction, and even if the manufacturer never engaged in *any* sales transaction in Maine leading up to that retail purchase. It is undisputed that there are currently no drug manufacturers located in Maine, and that manufacturers make few (if any) sales to anyone in Maine, much less retail sales to consumers. Typically, pharmaceutical manufacturers sell drugs to national and regional wholesalers (all but one of which are also outside Maine) in transactions that take place in other states.

The "rebate" required from a manufacturer has no relationship to the in-state sales price. Instead, it is tied to a national price benchmark: the Maine Commissioner of Human Services is instructed to use his best efforts, backed by the sanctions of the Maine law, to secure a rebate on each

drug that is at least as large as the rebate that the manufacturer pays nationwide in the federal Medicaid program.[1] (The Medicaid rebate, in turn, is a function of the manufacturer's average price to customers nationwide, or of its single best price to any commercial customer in the country.) Implementing the Act's mandate, Respondent Concannon presented manufacturers with a form Maine Rx Rebate Agreement, for signature no later than November 1, 2000, that dictated payment of "the Medicaid Rebate amount." (JA 64, 67)[2]

Manufacturer "rebate" payments are to be paid into a dedicated state fund, which Maine will use to reimburse local pharmacies for prescription drug discounts for participating Maine residents.[3] Maine makes no net contribution to these subsidies; they are to be funded entirely by the payments extracted from manufacturers.

2. The Act enforces its requirement that manufacturers pay for these Maine Rx subsidies by

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[1] The federal Medicaid program pays for Medicaid beneficiaries' prescription drugs using federal and state funds. For their drugs to be covered in this program, manufacturers must pay a per-unit rebate based on Medicaid sales in each state. 42 U.S.C. § 1396r-8. The nationwide Medicaid rebate for a given drug is calculated based on data about the manufacturer's pricing around the country, using a formula set forth in the Medicaid statute. 42 U.S.C. § 1396r-8(c)(1).

[2] Citations with the notation "JA" refer to items in the parties' Joint Appendix before the court of appeals.

[3] Maine residents will tender a "Maine Rx" card at the pharmacy, and will be charged a discounted price set by the state. The state will then use the funds obtained from manufacturers to reimburse pharmacies for those discounts, plus "professional fees" of at least $3 per prescription. 22 Me. Rev. Stat. Ann. § 2681(5), (6).

threatening them with sanctions under the federal Medicaid program if they do not. If a manufacturer refuses to pay Maine Rx rebates, its drugs will be subject to a "prior authorization" requirement in the Medicaid program in Maine. 22 Me. Rev. Stat. Ann. § 2681(7). A drug subject to "prior authorization" will not be covered by Medicaid unless a physician first obtains special permission from state Medicaid officials to prescribe it to a Medicaid patient. Prior authorization is commonly used to limit prescription of drugs that present medical risks or that are vulnerable to over-prescription, posing risks to the Medicaid patient or program. Here, however, the sole purpose of subjecting drugs to prior authorization is to reduce non-complying manufacturers' sales and thereby to coerce them into joining the Maine Rx program. Prior authorization achieves that effect by deterring doctors from prescribing the restricted drugs and inducing them to switch their patients to other, potentially second-choice, medications.

II. The District Court's Order

On August 10, 2000, PhRMA filed its complaint for declaratory and injunctive relief in the U.S. District Court for the District of Maine, claiming that the rebate provisions of the Act violated the Supremacy Clause and the Commerce Clause of the U.S. Constitution. On October 26, 2000, finding PhRMA's likelihood of success on the merits of these claims to be "overwhelming," the district court issued a preliminary injunction against the implementation of the Maine Rx rebate program. (App. 72)

Judge Hornby held that Maine had exceeded the territorial limits of its regulatory authority under the Commerce Clause. He found that, by exacting rebates from drug manufacturers who sell their drugs outside the state, the Maine Rx Program unavoidably—and unconstitutionally—regulates those out-of-state sales. (App. 64-66) The district court rejected Maine's efforts to escape

Commerce Clause scrutiny by claiming the status of a "market participant." (App. 64)

The district court also ruled that Maine's use of its Medicaid "prior authorization" power to penalize manufacturers who do not subsidize discounts under the separate Maine Rx program posed an obstacle to the delivery of Medicaid benefits. Because of that conflict, the district court found the use of prior authorization to enforce Maine Rx rebate collections to be preempted by the Medicaid statute. (App. 67-70)[4]

III. Proceedings in the First Circuit

On May 16, 2001, a First Circuit panel, sitting pursuant to an emergency certification under 28 U.S.C. § 46(b) and including no active judges of the court, reversed and vacated portions of the preliminary injunction—even while describing the appeal as a "close case." (App. 28)

The court of appeals held that, because the pharmacy sales of the drugs take place in Maine, it does not constitute "extraterritorial" regulation for Maine to require out-of-state manufacturers to subsidize those in-state retail sales, even

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[4] PhRMA also claimed in the district court that other so-called "anti-profiteering" provisions of the Act violated the Commerce Clause to the extent they purported to regulate transactions occurring outside Maine. *See* 22 Me. Rev. Stat. Ann. § 2697(2). The district court agreed and preliminarily enjoined their enforcement in connection with out-of-state transactions. (App. 60) Maine did not appeal from that portion of the district court's order, and hence the "anti-profiteering" provisions are not before this Court (except as evidence of the Act's compulsory design). The district court concluded that PhRMA's Commerce Clause challenge to a related "anti-retaliation" provision, prohibiting manufacturers from reducing or altering the distribution of drugs in Maine in response to the Act, was not ripe. (App. 61)

though the manufacturers sell their drugs, not to consumers or even pharmacies in Maine, but to wholesalers outside Maine.

The court also held that Maine's use of the Medicaid "prior authorization" sanction to compel payment of subsidies for *non*-Medicaid patients under Maine Rx does not conflict with the federal Medicaid program. The court declined to find such conflict in the absence of evidence that prior authorization must result in the denial of medically necessary drugs to Medicaid patients. (App. 16) The court also expressed the view that Maine Rx subsidies might benefit the Medicaid program indirectly by keeping some Maine residents from needing Medicaid assistance at some future date. (App. 13)

PhRMA timely filed a petition for rehearing *en banc*. The court of appeals' emergency panel denied the subsumed petition for rehearing, but announced in an order dated June 13, 2001, that "there can be no action taken" on the petition for rehearing *en banc* because all but one of the active judges of the court of appeals were recused. The one active judge of the First Circuit who was not recused—Chief Judge Torruella—stated that he supported rehearing *en banc* "based on the opinion of the District Court." (App. 55)

The court of appeals' decision constitutes a final judgment on the merits of Petitioner's Commerce Clause and Supremacy Clause challenges to the Act. On PhRMA's motion to stay the mandate pending filing of this petition, the court of appeals entered an order staying its mandate until July 31, 2001.

REASONS FOR GRANTING THE WRIT

I. The First Circuit's Decision on the Medicaid Issue Is in Error, and Conflicts with a Decision of the D.C. Circuit.

The First Circuit's conclusion that Maine may use its authority under the federal Medicaid statute to compel drug manufacturers to provide discounts to individuals not eligible for Medicaid is both incorrect and in conflict with a decision of the D.C. Circuit. The D.C. Circuit held that Congress in the federal Medicaid statute does not authorize states to compel drug manufacturers to pay for Medicaid discounts for non-Medicaid populations.

A. The First Circuit Erred in Holding that the Federal Medicaid Statute Allows a State To Require Manufacturers To Provide Discounts for Non-Medicaid Populations.

In the Medicaid program, a prescribing physician must contact the state Medicaid authority and provide written documentation to justify prescribing a "prior authorized" drug to his or her Medicaid patient. *See* Maine Medical Assistance Manual, Ch. II § 80.07-3, -4 (JA 177-79). The burden of obtaining prior authorization deters—indeed, is designed to deter—physicians from prescribing the drugs in the first instance. Medicaid beneficiaries' access to their doctors' preferred drugs is therefore necessarily impeded. (JA 122-25)

Prior authorization has legitimate uses in the Medicaid program. It can, for example, be used to prevent abuse or over-prescription of popular but expensive medications, thereby benefiting Medicaid patients and promoting Medicaid's cost-effective operation. Although prior authorization restricts the provision of physicians' first-choice drugs to Medicaid patients, that burden is deemed to be outweighed by the benefits to the Medicaid program.

The federal Medicaid statute authorizes states to impose prior authorization requirements for prescriptions paid for by Medicaid, subject to certain procedural safeguards. 42 U.S.C. § 1396r-8(d)(1), (5).

Here, the purpose of the Act's imposition of Medicaid prior authorization is not to benefit the federal Medicaid program or Medicaid beneficiaries, but to coerce funding by drug manufacturers of an unrelated state program. Because Medicaid prior authorization by definition restricts the delivery of drug benefits to Medicaid patients, its imposition to effectuate the Maine Rx program both burdens and conflicts with the Medicaid program.

This court's jurisprudence is clear: state laws that impose "obstacles to the accomplishment and execution of the Congressional objectives" of the federal law—here, Medicaid—cannot stand. *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983). This is just such a law. Congress intended to provide prescription drugs to Medicaid patients, a class identified by federal law that does not extend to the entire citizenry of Maine. *See* 42 U.S.C. § 1396, 1396a(a)(10)(A), 1396d(a). The flow of those prescription drug benefits will be restricted by the state under Maine Rx.

The court of appeals misunderstood the nature of the "obstacle" or "interference" with the Medicaid program that Maine Rx causes. Depriving patients of necessary drugs or directly harming their health would of course offend the Medicaid statute. But it is not necessary to await evidence of actual, life-threatening harms to Medicaid patients in order to find that Maine Rx prior authorization interferes with Medicaid's provision of medical services to Congress's intended beneficiaries. *See* 42 U.S.C. § 1396, 1396r-8. Failure to pay Maine Rx rebates will trigger prior authorization of at least *some* drugs—drugs that, "but for" Maine Rx, would be accessible to Medicaid patients and doctors without delay, and paid for by Medicaid without

reservation. This interference with the physician's choice of treatments for Medicaid patients is inherent and inescapable in the structure of the program. The physician is now forced to choose between a first-choice drug that requires prior authorization and a second-choice drug that does not. Maine Rx-triggered prior authorization also consumes federally-funded Medicaid resources, such as the time and resources of the Medicaid Drug Utilization Review Committee that lists drugs for prior authorization, and of the Medicaid officials who must review doctors' prior authorization requests.

Without a Medicaid purpose, the Maine Rx use of prior authorization is necessarily inconsistent with the "best interests" of Medicaid patients, 42 U.S.C. § 1396a(a)(19), and the Medicaid program. The court of appeals mistakenly required factual proof of realized harms to patients. No such human experimentation should be required to recognize that Maine Rx prior authorization is preempted as a matter of law, for the program cannot possibly be in the "best" interests of Medicaid patients if it serves *no* interest of the Medicaid program.

In reversing the district court, the court of appeals found it significant that the Medicaid statute does not expressly bar states from co-opting Medicaid prior authorization authority for non-Medicaid purposes. But the lack of an express prohibition on using Medicaid powers for non-Medicaid purposes is no license to do so. As the district court recognized, the logical implication of that approach—that Medicaid prior authorization can be put to *any* purpose—is stunning: "If Maine can use its authority over Medicaid authorization to leverage [rebates for Maine Rx], then it can just as easily put the rebates into a state program for highway and bridge construction or school funding." (App. 68) Congress cannot be deemed to have allowed the tools it provided for the operation of the federal

Medicaid program to be used for any other purpose that a state may imagine.

The court of appeals reasoned that Maine Rx subsidies might indeed serve a "Medicaid purpose" by reducing impoverishment, thus keeping Maine residents off Medicaid rolls. (App.13) The same reasoning, however, would permit Maine to compel drug manufacturers to subsidize public housing, job training programs, and any number of other public projects that would boost Maine residents' income and keep them off Medicaid. There is simply no suggestion that Congress intended to permit states to put Medicaid beneficiaries' access to prescription drugs at risk in order to fund other budget items or promote local non-Medicaid social goals. That Congress did not affirmatively prohibit states from doing so is insufficient to defeat an "obstacle" preemption claim, and in any event, is explicable by the fact that Maine's forced subsidy so far departs from the Medicaid program that Congress could not have been expected to foresee and prohibit it. As Judge Hornby explained, "[i]t may never have occurred to Congress that the Medicaid program could by hijacked to provide leverage for other purposes." (App. 69 n.12)[5]

B. The First Circuit's Decision Conflicts with a Decision of the D.C. Circuit.

The First Circuit's holding that a state may use its authority under the federal Medicaid statute to require drug manufacturers to provide discounts to non-Medicaid consumers is also incompatible with a recent ruling of the

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[5] The limited legislative history of the Medicaid drug benefit and the federal Health Care Financing Agency's ("HCFA") proposed implementing regulations contemplate the use of prior authorization only in narrow circumstances, all of which further Medicaid objectives. *See* the district court's exposition of this history at App. 69 n.12.

Court of Appeals for the District of Columbia Circuit. That court, in *PhRMA v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001), held that Congress has *not* authorized the U.S. Department of Health and Human Services ("HHS") to permit states to "require pharmaceutical manufacturers to provide substantial discounts to individuals not otherwise covered by state Medicaid programs." 251 F.3d at 226. If the federal Medicaid statute does not authorize HHS to permit a state to require manufacturers to subsidize discounts to non-Medicaid populations, the statute cannot be meant to empower states like Maine to impose such requirements on manufacturers directly.

In *Thompson*, Vermont—like Maine—sought to extend Medicaid prescription drug discounts to individuals who were not eligible for Medicaid benefits. Rather than use Medicaid prior authorization to exact drug rebates in a non-Medicaid program, Vermont obtained a statutory waiver from HHS authorizing it to obtain rebates for non-Medicaid patients directly under the auspices of the Medicaid program. PhRMA challenged Vermont's waiver, whose intent and effect were identical to those of the Maine Rx program: the state would use authority under the Medicaid program (waiver authority in Vermont, prior authorization authority in Maine) to compel drug manufacturers to fund Medicaid-level discounts for patients not covered by the Medicaid program.

The D.C. Circuit held that the federal Medicaid statute does not permit such a scheme; the First Circuit held that it does. The decisions of the First and D.C. Circuits are therefore in conflict. Specifically, the First Circuit held that Maine may administer the Medicaid program in a manner that extends Medicaid benefits to non-Medicaid populations; the D.C. Circuit concluded that the Medicaid statute did not authorize HHS or Vermont to secure Medicaid discounts from drug manufacturers for non-Medicaid patients. The

First Circuit permitted Maine to stretch its Medicaid authority to extra-Medicaid ends; the D.C. Circuit denied that leeway to HHS and Vermont.

Review by this Court is necessary to resolve this conflict in federal statutory interpretation. Even though the D.C. Circuit case concerned the scope of administrative authority to permit state action pursuant to Medicaid while this case concerns that of a state in the first instance, the underlying issue is identical: may the leverage of Medicaid be used to compel subsidies from manufacturers for persons outside the Medicaid program. The D.C. Circuit correctly answered that question in the negative, and the petition should be granted here to ensure that the same answer applies nationwide. The Medicaid program operates throughout the country, providing medical care to millions of beneficiaries. Many more states have announced plans to enact their own versions of the Maine Rx program (*see* Part III *infra*). Interpretations of the scope of Medicaid statutory authority on a matter of such national importance should not be permitted to vary from one circuit to the next.

II. The Decision Below Allows the State to Circumvent the Commerce Clause's Prohibition Against State Regulation of Wholly Out-of-State Transactions.

The court of appeals permitted Maine to circumvent the Commerce Clause's prohibition against extraterritorial regulation. Few prohibitions of the structure of federalism are so clear or compelling as the one that a state may not regulate economic transactions that take place beyond its borders. Whether the Maine Rx program is characterized as an extraterritorial regulation of price or of revenue, as an impermissible tie between in-state and out-of-state prices, or as akin to a tax, it violates that prohibition. Thus, Maine's requirement that out-of-state manufacturers, who sell their products to out-of-state wholesalers in wholly out-of-state transactions, remit a portion of the out-of-state sales price to

subsidize in-state retail purchases by Maine residents runs afoul of the negative implications of the Commerce Clause.

A. The Maine Rx Rebates Regulate Wholly Out-of-State Transactions

It is axiomatic that a state "has no power to project its legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there." *Baldwin v. G.A.F. Seelig*, 294 U.S. 511, 521 (1935) (internal punctuation omitted). As this Court has repeatedly confirmed, a state may not dictate the terms on which buyers and sellers do business outside the state. *See, e.g., Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 583-84 (1986); *Healy v. The Beer Institute*, 491 U.S. 324, 338 (1989). Three factors help identify a state statute with an unconstitutional extraterritorial reach or effect that will render it virtually *per se* invalid: (i) whether the regulation is applied to commerce "wholly outside of the State's borders," (ii) whether "the practical effect" of the regulation is to control such commerce, and (iii) what effect the regulation has on other states' regulations, as well as what effect would result "if not one, but many or every, State adopted similar legislation." *Healy*, 491 U.S. at 336.

Consistent with these teachings, states may not regulate the price or terms on which goods are sold outside the state simply because the goods are later re-sold within the state. Rather, the courts have limited the reach of a state's powers to transactions that actually take place within the state. *See Baldwin*, 294 U.S. at 528; *Dean Foods Co. v. Brancel*, 187 F.3d 609, 614-15 (7th Cir. 1999); *Louisiana Dairy Stabilization Bd. v. Dairy Fresh Corp.*, 631 F.2d 67 (5th Cir. 1980); *Schwegmann Bros. Giant Super Mkts. v. Louisiana Milk Comm'n*, 365 F. Supp. 1144, 1156 (M.D. La. 1973), *aff'd mem.* 416 U.S. 922 (1974).

The court of appeals' decision would allow Maine to circumvent the Commerce Clause prohibition delineated in

these cases. The Act regulates manufacturers' sales outside the state, and thus impermissibly extends that State's reach extraterritorially. But Maine seeks to reach these out-of-state sales under the guise of regulating the in-state sales that follow from them.

Virtually all manufacturers' sales of prescription drugs occur outside of Maine, in direct, arms-length transactions with wholesalers and distributors. Typically, both the manufacturers and their customers (independent wholesalers and distributors) are located outside Maine. More important, the drugs are usually delivered at the manufacturers' facilities outside Maine, and title and risk of loss pass outside Maine. Frequently the drugs are then shipped by common carrier to warehouses and distribution centers outside Maine. (JA 54-55, 57-58, 75-76, 87-88, 100-01) The wholesalers and distributors then sell the drugs to their customers, including customers in Maine.

Nevertheless, Maine Rx will exact a payment from a drug's manufacturer every time the drug crosses the pharmacy counter in Maine, even though the out-of-state manufacturer sold that product outside Maine to a wholesaler in another state and had no further role in the transactions that took the drugs to Maine. That levy necessarily changes the economic terms of the only sales transactions in which manufacturers *are* engaged—namely, sales outside the State—by effectively reducing the revenues the manufacturers receive for their products from their wholesale customers. The manufacturer who is assessed the rebate will receive less net revenue on each wholesale transaction involving drugs that find their way to Maine (a result the manufacturer does not control and cannot predict). As the district court recognized, "whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced when the drug comes to Maine." (App. 66) Whether Maine is understood as regulating price or revenue in manufacturers' out-of-state

wholesale transactions, it is impermissibly regulating outside its borders.

The court of appeals erred in treating the Act as "simply regulat[ing] activity that occurs in state"—namely the consumer's retail purchase of drugs at a Maine pharmacy. (App. 24) That retail sale of a drug in Maine serves only as the trigger for the required rebate. What matters for Commerce Clause analysis is the target of the regulation—the manufacturer—and where that target does its business. The out-of-state manufacturer is a stranger to the "triggering" in-state transaction at the pharmacy. The court ignored the fact that the manufacturer is remote from that triggering event and that the "practical effect" of the Act is to regulate the manufacturer's commerce occurring "wholly outside of the state's borders." *Healy*, 491 U.S. at 336. The court of appeals thus incorrectly allowed Maine to circumvent the Commerce Clause's prohibition on extraterritorial regulation.

The court of appeals attempted to distinguish *Healy*, *Brown-Forman*, and *Baldwin* on the ground that they prohibit only the express regulation of out-of-state price terms, not the regulation of manufacturers' profits in out-of-state sales. (App. 22) This distinction presents a novel question warranting this Court's attention: is the dormant Commerce Clause's bar on extraterritorial regulation limited solely to the explicit regulation of price terms? May a state evade the bar of *Healy*, *Brown-Forman*, and *Baldwin* by explicitly regulating only the non-price terms of out-of-state transactions?

Nothing in the *Healy* line of cases suggests that the extraterritoriality prohibition is limited to extraterritorial price controls. To the contrary, *Healy* simply holds that a state law with the "'practical effect' of regulating commerce occurring wholly outside the State's borders" is *per se* invalid under the Commerce Clause. 491 U.S. at 332. The term "commerce" is not restricted to price. For example,

this Court has also struck down as extraterritorial a business takeover act that lacked any pricing dimension whatsoever, in *Edgar v. MITE Corp.*, 457 U.S. 624 (1978).

If a state is barred from regulating prices out-of-state, it surely should not be free to achieve the same effect by regulating quantity, profit or other ancillary terms of sale instead. The court of appeals' distinction between the regulation of out-of-state price terms (which this Court has held to be prohibited) and the regulation of out-of-state revenue (which the First Circuit would permit) makes no economic sense. Absent intervention by this Court, the First Circuit's flawed distinction will stand as a new—and erroneous—principle of dormant Commerce Clause jurisprudence.

Maine had any number of constitutionally legitimate tools at its disposal for reducing drug costs for its citizens. It might constitutionally have raised funds for the Maine Rx program by imposing a tax on retail pharmacy sales within the state. It might constitutionally have entered the pharmaceutical market as a wholesale purchaser, exercising its own market power to reduce retail prices through bulk purchases—a form of market participation the court of appeals correctly found not present in the Act, *see* App. 20. But Maine chose to do none of these things, and instead attempted to circumvent the Commerce Clause. That attempt should not be permitted to succeed.[6]

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[6] Given the high degree of integration in our national economy, it is especially dangerous to permit the kind of fragmentation Maine proposes—namely, allowing states to compel in-state subsidies by upstream manufacturers doing business in other states. Other issues may soon capture a state legislature's attention—*e.g.*, levies on Texas oil refiners to fund New Hampshire heating oil subsidies, or compulsory rebates from California chip manufacturers to reduce the price of computers in New Jersey. According to the court of appeals, the Commerce

B. The Maine Rx Rebates Are Impermissibly Tied to Out-of-State Prices

The First Circuit's refusal to apply this Court's extraterritoriality precedents is even more disturbing in light of the fact that the Act *does* have the effect of regulating out-of-state prices. Like the state laws at issue in *Baldwin*, *Healy*, and *Brown-Forman*, the Act expressly ties in-state prices to out-of-state prices. It specifies that the rebate required of manufacturers shall equal or exceed the rebates required around the country under Medicaid and other federal programs. 22 Me. Rev. Stat. Ann. § 2681(3), (4).

This use of an out-of-state price benchmark for Maine's in-state mandatory rebate offends the Commerce Clause in just the ways noted in *Brown-Forman* and *Healy*: the regulated business can no longer set its out-of-state price based solely on the out-of-state market conditions. Instead, when setting prices in out-of-state (or here, federal and nationwide) transactions, the drug manufacturers now must also factor the in-state price ramifications into their pricing calculations.[7] Such price-tying has been explicitly condemned as *per se* invalid by this Court because it

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Clause places no limits on a state's extraterritorial reach or its creativity, so long as a good is ultimately sold within that state.

[7] The federal prices to which Maine Rx rebates are tied are variable, and change with manufacturers' commercial pricing decisions. Specifically, the federal Medicaid rebate amount for each brand-name drug is a function of the manufacturer's national average price to retail customers and the manufacturer's "best price" to any commercial customer in the country. 42 U.S.C. § 1396r-8(c)(1). Although calculated under a statutory scheme, these "national prices" that set the benchmarks for Maine Rx rebates are susceptible to the same market pricing dynamics and extraterritorial effects as the state-specific prices described in *Healy* and *Brown-Forman*.

interferes with market-based competition in the out-of-state markets. *See, e.g., Healy*, 491 U.S. at 332.

The court of appeals did not consider the Commerce Clause's prohibition on extraterritorial price-tying to be violated because the Act directs the Commissioner to use his "best efforts" to "negotiate" the rebate, and does not unequivocally dictate that price. But the reality is that there is nothing to "negotiate"—in the Act's own words, the "rebate [is] *required* from a manufacturer" under an agreement that the manufacturer "*shall enter into*." 22 Me. Rev. Stat. Ann. § 2681(3), (4) (emphasis supplied). Even more powerfully, if a manufacturer refuses to pay the rebate, its drugs become subject to prior authorization. Putting form over substance, the court of appeals again permitted the state to evade the strictures of the Commerce Clause.

C. The Maine Rx Rebates Tax Wholly Out-of-State Transactions

The court of appeals' decision also allows Maine to circumvent another line of Commerce Clause precedents: *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977), and its companion tax cases. While not ostensibly a tax or duty, the Maine Rx rebate requirement has the same effect as a sales tax or import assessment on the manufacturer's products—it demands payment to the state for each unit of the manufacturer's goods that are sold in Maine pharmacies.[8] Analogizing the Act to a tax further

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[8] Maine has declined to characterize the Maine Rx program as a state tax or a duty on imports (JA 228); rather, the parties invoked the interstate tax immunity cases to illuminate the issues here by analogy. Although the court of appeals declined to address this line of argument (App. 27 n.11), it was briefed and argued by both parties below. *Cf. Nixon v. Fitzgerald*, 457 U.S. 731, 743 n.23 (1982) (Court may decide purely legal question not passed on below).

underscores the court of appeals' error in allowing Maine to circumvent this Court's Commerce Clause precedents.

The *Complete Auto* line of decisions establishes that the mere fact that a product winds up within the state is an insufficient basis upon which to impose a tax on out-of-state entities. *Id.* at 277-79. The Maine Rx rebate thus lacks the "'definite link . . . between a state and the person, property or transaction it seeks to tax'" that the Commerce Clause requires. *National Bellas Hess v. Department of Revenue of Ill.*, 386 U.S. 753, 756 (1967) (quoting *Miller Bros. Co. v. Maryland*, 347 U.S. 340, 344-45 (1954)) (overruled in part on other grounds, *Quill Corp. v. North Dakota*, 504 U.S. 298 (1992)); *see also Complete Auto*, 430 U.S. at 277-79 (requiring a tax to be "applied to an activity with a substantial nexus with the taxing State" to satisfy the Commerce Clause).

This Court has "more than once . . . struck down taxes directly imposed on or resulting from out-of-state sales which were held to be insufficiently related to activities within the taxing State, despite the fact that the vendor knew that the goods were destined for use in that State." *American Oil Co. v. P.G. Neil*, 380 U.S. 451, 457 (1965) (citations omitted). As with regulatory power generally in *Baldwin* and *Healy*, the Commerce Clause places a territorial limit upon the state's taxation power. *See Bellas Hess*, 386 U.S. at 759 (vendor whose only contacts with taxing state are by mail or common carrier lacks substantial nexus required by Commerce Clause).

States may require payments from out-of-state firms in connection with those firms' commercial transactions *within the state*. However, they may not collect sales taxes from out-of-state firms in connection with sales that are wholly outside of the state. The Maine Rx law exacts payments from manufacturers, even when they are not responsible for delivering their products to, and are strangers to the triggering retail sales within, the state. Indeed, it does so

even when those retail transactions involve no physical presence of the manufacturer in Maine.[9] The State thus attempts to "tax" manufacturers' out-of-state activities even where their "taxed" drug sales have no nexus at all, much less a substantial one, with the State of Maine.

When Maine exacts Maine Rx rebates on manufacturers' out-of-state transactions, merely because the drugs sold wind up crossing a pharmacy counter in Maine, the Act's rebate requirement necessarily fails the *Complete Auto* Commerce Clause test for taxes. *See Complete Auto*, 430 U.S. at 277-79; *see also Quill*, 504 U.S. at 311; *Bellas Hess*, 386 U.S. at 759; *P.G. Neil*, 380 U.S. at 457-58. This is an independently sufficient basis for this Court's review.

III. The Statutory and Constitutional Questions Are of National Importance in Light of Pending Legislation in Dozens of States

The national import of this case is easily demonstrated. In the absence of a federal-level drug benefit for the elderly, many states anxious to make prescription drugs more affordable for their citizens wait in the wings with legislation modeled on Maine Rx. They are watching this case to resolve the current conflict in the circuits regarding Medicaid's scope, and to clarify the Commerce Clause boundaries of their authority. Were this Court to decline review, it would give these dozens of states a green light to copy Maine's program, rapidly multiplying the constitutional and commercial harms that the Maine Rx

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[9] While manufacturers' other activities in Maine (advertising, direct sales that do not trigger Maine Rx rebates, *etc.*) might constitute sufficient minimum contacts with the state for Due Process purposes, they do not establish the requisite "substantial nexus" with Maine for Commerce Clause purposes in imposing a tax on manufacturers' out-of-state transactions. *See Quill*, 504 U.S. at 312-13.

program inflicts, and leading to proliferating litigation in the lower courts.

The Center for Policy Alternatives, a non-profit think tank serving state legislators, state policy organizations, and state grassroots leaders, for example, is promoting model prescription drug pricing legislation whose text is a nearly verbatim replica of the Maine Rx law—state legislatures need only fill in the blank with the state's name to create a copycat "State Rx" program.[10] By the Center's count, some 27 states have taken steps to do so.[11] The National Conference of State Legislatures reports that over 40 states are considering price-related prescription drug legislation.[12]

The proposed "Alabama Prescription Drug Fair Pricing Act" is just one such example. Like Maine's Act, it provides that drug manufacturers "shall enter into" rebate agreements, that state officials "shall obtain" rebates equal to or greater than Medicaid rebates, and that the state "shall impose prior authorization requirements in the state Medicaid program" on the drugs of manufacturers who do not pay the mandated rebates. *See* H.B. 1, 2001 Reg. Sess. (Ala. 2001). Nearly identical bills have also been introduced this year in Arkansas, Hawaii, Louisiana, Minnesota, Oregon, Pennsylvania, and Tennessee. *See* H.B.

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[10] *See* Center for Policy Alternatives, *Model Legislation: Prescription Drug Fair Pricing Act*, *at* http://www.stateaction.org/issues/healthcare/prescription/fairpricemodel.cfm.

[11] *See* Center for Policy Alternatives, *States Poised to Lower Prescription Drug Prices as First Circuit Court of Appeals Rules Against PhRMA* (May 17, 2001), *at* http://www.stateaction.org/cpa/pressroom/archives/prcomplete.cfm?ID=139.

[12] *See* National Conference of State Legislatures, *2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation*, *at* http://www.ncsl.org/programs/health/drugdisc01.htm (last modified July 24, 2001).

1925, 83rd Leg., Reg. Sess. (Ark. 2001); H.B. 47, 2001 Reg. Sess. (Haw. 2001); H.B. 1089, 2001 Reg. Sess. (La. 2001); H. 944, S. 765, 82d Leg., Spec. Sess. (Minn. 2001); S. 877, 71st Leg., Reg. Sess. (Ore. 2001); H.B. 444, 2001 Gen. Assem., Reg. Sess. (Pa. 2001); H. 123, S. 19, 102d Gen. Assem., Reg. Sess. (Tenn. 2001).[13]

The bills just described are those that most closely replicate the Maine Rx program. Many other states, however, are pursuing mandatory Maine Rx-style discounts or "rebate agreements" in other forms. Expanded access to prescription drugs is at the top of the national policy agenda, and the political and media debates fuel state initiatives like the ones above. However desirable national public policy attention to this issue may be, states may not in the meantime balkanize the national economy by regulating manufacturers' sales outside their borders, or leverage authority under the Medicaid statute to serve non-Medicaid populations.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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[13] In addition, bills in a number of state legislatures this year replicate many but not all aspects of the Maine Rx Act. *See* H.B. 5050, 2001 Gen. Assem., Jan. Sess. (Conn. 2001); H.B. 2236, 92d Gen. Assem. (Ill. 2001); H.B. 2026, 112th Gen. Assem., 1st Reg. Sess. (Ind. 2001); H.B. 2692, 2001 Gen. Assem., Reg. Sess. (Va. 2001); H.B. 1073, 57th Leg., 1st Spec. Sess. (Wash. 2001).

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July 31, 2001

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 00-2446

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff, Appellee,
v.
KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, and MAINE ATTORNEY GENERAL,
Defendants, Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE
[Hon. D. Brock Hornby, *U.S. District Judge*]

Before
Bownes, *Senior Circuit Judge*,
Keeton and Saris*, *District Judges*.

Andrew S. Hagler, Assistant Attorney General, with whom *G. Steven Rowe*, Attorney General, *Paul Stern*, Deputy Attorney General, *John R. Brautigam*, Assistant Attorney General, *Cabanne Howard*, and *University of Maine Law School*, were on brief, for appellant.

Thomas C. Bradley, *Arn H. Person* and *Maine Citizen Leadership Fund* on brief for Viola Quirion, Michelle Campbell, Maine Council of Senior Citizens and Richard Donahue, M.D., amici curiae.

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* Of the District of Massachusetts, sitting by designation.

Kathleen M. Sullivan, with whom *Daniel M. Price, Allen S. Rugg, Marinn F. Carlson, Powell, Goldstein, Frazer & Murphy, L.L.P., Bruce C. Gerrity* and *Preti, Flaherty, Beliveau, Pachios & Haley L.L.C.,* were on brief, for appellees.

Daniel J. Popeo, Richard A. Samp and *Washington Legal Foundation,* on brief for Washington Legal Foundation, Allied Educational Foundation, International Patient Advocacy Association, Kidney Cancer Association, The Seniors Coalition, and The 60 Plus Association, amici curiae.

Steven J. Rosenbaum, David H. Remes, Covington & Burling, Robin S. Conrad and *National Chamber Litigation Center* on brief, for the Chamber of Commerce of the United States, amicus curiae.

Edwin D. Schindler on brief *pro se*, amicus curiae.

May 16, 2001

BOWNES, *Senior Circuit Judge*. In this case, we consider whether a Maine statute providing for affordable prescription drugs can survive facial constitutional challenges. On October 26, 2000, the district court issued a preliminary injunction preventing the implementation of the statute on the ground that it is preempted by the Supremacy Clause and violates the dormant Commerce Clause. We reverse.

I. BACKGROUND

On May 11, 2000, the Governor of Maine signed into law an Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S. P. 1026) (L. D. 2599)

(the "Act"), which establishes the "Maine Rx Program" (the "Program").[1]

The statute was enacted because of the Maine Legislature's concern that many Maine citizens who were not Medicaid recipients could not afford necessary prescription drugs. It is predicated on the economic reality that volume buying of prescription drugs by Medicaid administrators, insurance companies and health maintenance organizations ("HMOs") resulted in substantially lower prices for these entities than for individual purchasers. A minority staff report for the United States House Committee on Government Reform and Oversight found that the average retail price for individual elderly purchasers was 86 percent higher than the price charged to the federal government and other favored customers, such as HMOs.

The Program is open to all State residents, and allows enrollees to purchase prescription drugs from participating Maine pharmacies at a discounted price. The discount offered by the pharmacies is reimbursed by the State out of a dedicated fund created with the money raised from "rebate payments" collected from participating drug manufacturers. Me. Rev. Stat. Ann. tit. 22, § 2681. The obligation to pay the "rebate" is triggered by the retail sale of the manufacturer's drugs to a Program enrollee through a participating pharmacy.

The Act directs the Commissioner of Maine's Department of Health Services to negotiate rebate agreements with manufacturers. *Id.* § 2681(3). These rebate agreements are similar in form to the rebate agreements required of manufacturers participating in the Maine Medicaid outpatient drug program. *Id.* § 2681(4). In negotiating the rebate, the Commissioner is directed to

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[1] The full text of the relevant provisions of the Act is set forth in the Appendix, *infra*.

"consider" the rebate amount calculated under the Federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8, and to use his or her "best efforts" to obtain an initial rebate in the same amount. Me. Rev. Stat. Ann. tit. 22, § 2681(4)(A)-(C). Rebate payments are made quarterly on the basis of retail sales records for that quarter. *Id.* § 2681(3).

In order to create an incentive for manufacturers to enter rebate agreements with the Commissioner, the Act provides that names of manufacturers who do not enter into agreements be released to health care providers and the public. *Id.* § 2681(7). More importantly, the drugs of all noncompliant manufacturers are required to be subject, "as permitted by law," to the "prior authorization requirements" in the State Medicaid program. *Id.* § 2681(7). When subjected to prior authorization, a drug may not be dispensed to a Medicaid beneficiary without the approval of the State Medicaid administrator.

The plaintiff-appellee, Pharmaceutical Research & Manufacturers of America ("PhRMA"), brought an action in the United States District Court in the District of Maine against defendant-appellants Commissioner of the Maine Department of Human Services and the Maine Attorney General, challenging the constitutionality of the Act. PhRMA claimed that the Act violated the dormant Commerce Clause and was preempted by the federal Medicaid statute under the Supremacy Clause, and moved for a preliminary injunction to prevent the implementation of the Act.

The district court issued the preliminary injunction and found the Act unconstitutional on the two asserted grounds. First, the district court held that the Act had an impermissible extraterritorial reach by regulating the revenues out-of-state pharmaceutical manufacturers receive when selling to out-of state pharmaceutical distributors, thereby violating the dormant Commerce Clause. As to those distributors located in the State of Maine, the district

court held that the Act was preempted under the Supremacy Clause because it conflicted with the federal Medicaid program.[2]

II. DISCUSSION

A. Standard of Review

"The criteria for the grant of a preliminary injunction are the familiar four: likelihood of success, risk of irreparable harm, the balance of equities and the public interest." *Langlois v. Abington Hous. Auth.*, 207 F.3d 43, 47 (1st Cir. 2000) (citing *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 15 (1st Cir. 1996)). When a district court's grant of a preliminary injunction is appealed, our standard of review depends on the issue under consideration: we review pure issues of law de novo, findings of fact for clear error, and "judgment calls" with considerable deference. *Id.* (noting that our standard of review is sometimes summarized as being for "abuse of discretion").

The district court concluded that PhRMA's likelihood of success on the merits of most of its constitutional challenges was "overwhelming." Accordingly, it dealt only cursorily with the remaining preliminary injunction factors. Our review also focuses on PhRMA's likelihood of success on the merits of its challenges under the Supremacy Clause and the Commerce Clause. *See Weaver v. Henderson*, 984

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[2] The Act also contained a provision that made it "illegal profiteering" for a manufacturer to "exact[] or demand[] an unconscionable price" or to "exact[ ] or demand[ ] prices or terms that lead to any unjust or unreasonable profit." An Act to Establish Fairer Pricing for Prescription Drugs, § 2697(2), 2000 Me. Legis. Ch. 786 (S. P. 1026) (L.D. 2599) (to be codified at Me. Rev. Stat. Ann. tit. 22, § 2697(2)). The district court found this provision unconstitutional. The State of Maine has not appealed this ruling.

F.2d 11, 12 (1st Cir. 1993) (stating that the "sine qua non" of preliminary injunction analysis is whether plaintiff is likely to succeed on merits of claim).

B. Standing

The initial question we face is whether PhRMA has prudential standing to challenge the prior authorization provision of the Act. PhRMA contends that Maine's standing argument was not briefed to the district court, and therefore was waived. We assume, without deciding, that Maine may assert this standing challenge on appeal, and hold that PhRMA falls within the relevant "zone of interest."[3]

The Supreme Court recently reiterated the standard for determining prudential standing:

> [I]n applying the "zone of interests" test, we do not ask whether, in enacting the statutory provision at issue, Congress specifically intended to benefit the plaintiff. Instead, we first discern the interests "arguably . . . to be protected" by the statutory provision at issue; we then inquire whether the plaintiff's interests affected by the agency action in question are among them.

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[3] There is some dispute among the circuits as to whether prudential standing (as opposed to Article III standing) can be raised for the first time on appeal. *Compare Animal Legal Def. Fund v. Espy*, 23 F.3d 496, 499 (D.C. Cir. 1994) (prudential standing is non-waivable); *Thompson v. County of Franklin*, 15 F.3d 245, 248 (2d Cir. 1994) (same); *Cmty. First Bank v. Nat'l Credit Union Admin.*, 41 F.3d 1050, 1053 (6th Cir. 1994) (same) with *Pershing Park Villas Homeowners Ass'n v. United Pac. Ins. Co.*, 219 F.3d 895, 899 (9th Cir. 2000) (prudential standing is waivable); *Lindley v. Sullivan*, 889 F.2d 124, 129 (7th Cir. 1989) (same) Because we hold that Maine's challenge to PhRMA's standing would be unsuccessful in any event, as explained *infra*, it is not necessary for us to decide the waiver issue now.

Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co., 522 U.S. 479, 492 (1998).

Maine contends that PhRMA's interest is purely financial and is limited to ensuring that its members' drugs are prescribed instead of competitors' drugs. Nothing in the Medicaid statute, Maine argues, suggests that Congress intended to protect sales of any particular drugs. *See Tap Pharms. v. U.S. Dep't of HHS*, 163 F.3d 199, 208 (4th Cir. 1998) (holding that pharmaceutical manufacturer lacked standing to challenge Medicare rules reducing reimbursement amounts paid for their products because manufacturer's financial interests were not within zone of interests protected by Medicare).

PhRMA has not asserted an action to enforce rights under the Medicaid statute, however, but rather a preemption-based challenge under the Supremacy Clause. In this type of action, it is the interests protected by the Supremacy Clause, not by the preempting statute, that are at issue. *St. Thomas-St. John Hotel & Tourism Ass'n v. Virgin Islands*, 218 F.3d 232, 241 (3d Cir. 2000). As the Third Circuit recently pointed out, an entity does not need prudential standing to invoke the protection of the Supremacy Clause:

> We know of no governing authority to the effect that the federal statutory provision which allegedly preempts enforcement of local legislation by conflict must confer a right on the party that argues in favor of preemption. On the contrary, a state or territorial law can be unenforceable as preempted by federal law even when the federal law secures no individual substantive rights for the party arguing preemption.

Id. Thus, regardless of whether the Medicaid statute's relevant provisions were designed to benefit PhRMA, PhRMA can invoke the statute's preemptive force. *Cf.*

Burgio & Campofelice, Inc. v. N.Y. State Dep't of Labor, 107 F.3d 1000, 1006 (2d Cir. 1997) (concluding that the Supremacy Clause creates an implied right of action for injunctive relief against state officers who are threatening to violate federal law).

Given that PhRMA has prudential standing grounded in the Supremacy Clause, we think it may fairly assert the rights of Medicaid recipients for purposes of this action. Where a party has established a concrete injury in fact, and otherwise has standing to challenge the lawfulness of the statute, it is "entitled to assert those concomitant rights of third parties that would be 'diluted or adversely affected' should [its] constitutional challenge fail and the statute[] remain in force." *Craig v. Boren*, 429 U.S. 190, 195 (1976) (quoting *Griswold v. Connecticut*, 381 U.S. 479, 481 (1965)). Accordingly, "vendors and those in like positions have been uniformly permitted to resist efforts at restricting their operations by acting as advocates of the rights of third parties who seek access to their market or function." *Id.*, *see also* 1 L. Tribe, *American Constitutional Law*, §3-19, p. 438 (3d ed. 2000).

C. Preemption

Having decided that PhRMA has standing to challenge the Maine Act on preemption grounds, we now turn to the merits of that argument. The district court addressed preemption only with regard to the Act's regulation of sales to in-state distributors, after concluding that such regulation would not be barred by the Commerce Clause. It held that the prior authorization review requirement of the Act, Me. Rev. Stat. Ann. tit. 22, §2681(7), conflicted with the purposes of the Medicaid program such that the requirement was invalid under the Supremacy Clause.[4] If we affirm the

[4] Only the prior authorization review requirement of the Act is at issue for preemption purposes, not the public identification requirement. Therefore, for simplicity's sake, our use of the terms "the Act" or "Maine Rx Program" refer solely to the prior authorization review requirement.

district court's preemption holding, it would invalidate the Act as to all distributors, not just those who operate in Maine, and would obviate the need to address the Commerce Clause. Therefore, we analyze the issue of preemption first.[5]

Under the Supremacy Clause, a federal law may expressly or impliedly preempt state law. U.S. Const. art. VI, cl. 2 (stating that federal law "shall be the supreme law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"). As the parties agree, only "implied conflict preemption" is at issue here.[6]

[5] An amicus curiae brief offers another basis for federal preemption: Edwin D. Schindler, Major Stockholder and Patent Attorney, argues that the Maine Act is preempted by federal patent law. Because these issues were raised for the first time on appeal by an amicus, not by a party, we do not consider them. *Am. Fed'n of Gov't Employees, Local 3936 v. Fed. Labor Relations Auth.*, 239 F.3d 66, 69 (1st Cir. 2001); *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 6 (1st Cir. 1996) ("an amicus cannot introduce a new argument into a case").

[6] Express preemption of a state law occurs where "a federal statute explicitly confirms Congress's intention to preempt state law and defines the extent of that preclusion." *Grant's Dairy-Me., LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res.*, 232 F.3d 8, 15 (1st Cir. 2000). There is no explicit language in the Medicaid statute that forbids the Maine Rx Program. Nor is the doctrine of "field" preemption relevant, as Medicaid is a cooperative federal and state program. This form of implied preemption applies only when a federal regulatory scheme is so pervasive as to create the inference that Congress did not intend for the states to pass supplemental law in that area. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992). Therefore, we

Our task, therefore, is to consider if "compliance with both state and federal regulations is impossible" or if "state law interposes an obstacle to the achievement of Congress's discernable objectives." *Grant's Dairy-Me., LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res.*, 232 F.3d 8, 15 (1st Cir. 2000) (citing *Gade v. v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992)).

In doing so, we assume "that the historic police powers of the States [are] not to be superceded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." *Id.* at 14-15 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). We also recognize that federal preemption of a state law is "strong medicine," and is "not casually to be dispensed." *Id.* at 18. This is especially true when the federal statute creates a program, such as Medicaid, that utilizes "cooperative federalism": "Where coordinated state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one." *Wash., Dep't of Soc. & Health Servs. v. Bowen*, 815 F.2d 549, 557 (9th Cir. 1987) (quoting *N. Y. Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 421 (1973)).

To determine whether the state regulation is consistent with the federal statute, we examine the "structure and purpose of the [federal] statute as a whole." *Gade*, 505 U.S. at 98. The primary purpose of Medicaid is to enable states to provide medical services to those whose "income and resources are insufficient to meet the costs of necessary medical services . . . ." 42 U.S.C. §1396 (2000). Congress expressly intended that the provision of medical services be administered by the state "in a manner consistent with

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consider only implied conflict preemption as a basis for PhRMA's argument.

simplicity of administration and the best interests of the recipients." *Id.* § 1396a(a)(19).

We perceive no conflict between the Maine Act and Medicaid's structure and purpose. Neither the letter nor the intent of the Medicaid statute prevents states from imposing prior authorization requirements; indeed, they are explicitly permitted. 42 U.S.C. § 1396r-8(d)(1)(A) (states may "subject to prior authorization any covered outpatient drug"). The statute sets forth only two limitations on a state's use of prior authorization: the state must provide "response by telephone or other telecommunication device within 24 hours of a request for prior authorization;" and, with respect to most drugs, provide for "the dispensing of at least 72-hour [sic] supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary)." *Id.* § 1396r-8(d)(5)(A) and (B).

The plain text of the Maine Act appears to incorporate these Medicaid requirements. It provides: "The department shall impose prior authorization requirements in the Medicaid program under this Title, *as permitted by law*, for the dispensing of prescription drugs . . . ." Me. Rev. Stat. Ann. tit. 22, § 2681(7) (emphasis added). We read the language "as permitted by law" to limit the Act's application to only those situations in which prior authorization is permitted by Medicaid.[7] As the Department is charged with administering the Maine Rx Program, we owe deference to its interpretation of the Act. *Fireside Nissan, Inc. v. Fanning*, 30 F.3d 206, 212 (1st Cir. 1994).

Moreover, as set forth in the affidavit of Kevin Concannon, Commissioner of the Maine Department of

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[7] Kevin Concannon, Commissioner of the Maine Department of Human Services, affirms in an affidavit that the Department will not impose prior authorization that would conflict with the Medicaid requirements.

Human Services, Maine has proposed administrative rules governing prior authorization aimed at ensuring that Medicaid recipients will have access to needed medications. Specifically, the decision to place a drug on the prior authorization list may be made only by the State's Medicaid Drug Utilization Review [DUR] Committee, which exclusively comprises physicians and pharmacists licensed to prescribe or dispense medications in Maine. Concannon states:

> In making its determination of whether or not a prior authorization requirement is clinically appropriate, the DUR Committee shall be guided by the law of Medicaid, and particularly the principle that Medicaid recipients shall be assured access to all medically necessary prescription drugs.

PhRMA contends that prior authorization, however implemented, necessarily interferes with the delivery of Medicaid services by placing an administrative burden on physicians and patients. This interference is acceptable, it says, when performed in the usual course of the Medicaid regulations concerning prior authorization, 42 U.S.C. § 1396r-8(d)(5), because there is a countervailing "legitimate" purpose of preventing abuse or over-prescription of certain expensive medications. In the case of a prior authorization under the Maine Rx Program, however, PhRMA argues (and the district court agreed) that there is no "Medicaid purpose" or "benefit" to Medicaid that offsets the interference. Hence, it contends, only when a prior authorization is motivated by the refusal to enter into a Maine Rx Program rebate agreement is it preempted.

This argument is unpersuasive. First, we are not convinced that the Medicaid statute is concerned with the motivation behind imposing prior authorization, as long as the 24-hour response and the 72-hour drug-supply requirements, 42 U.S.C. § 1396r-8(d)(5), are satisfied.

Thus, even if the district court's conclusion that "Maine can point to no Medicaid purpose in this new prior authorization requirement" is true, it does not necessarily mean that the prior authorization scheme *conflicts* with the objectives of the Medicaid program. We see no basis for inflicting the "strong medicine" of preemption on a state statute that, in the absence of an actual conflict, merely fails to directly advance the purpose of the federal program.

Moreover, even assuming that this inquiry into the underlying objectives of the Act is appropriate, we disagree that the Act serves no purpose related to Medicaid. The purposes of the Medicaid statute, read broadly, are consonant with the purposes of the Maine Rx Program. First, the Maine Rx Program furthers Medicaid's aim of providing medical services to those whose "income and resources are insufficient to meet the costs of necessary medical services," 42 U.S.C. § 1396, even if the individuals covered by the Maine Rx Program are not poor enough to qualify for Medicaid. Second, there is some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures. When people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible. *See* Stephen B. Soumerai, Sc.D., Dennis Ross-Degnan, Sc.D., *Inadequate Prescription-Drug Coverage for Medicare Enrollees - A Call to Action,* New England Journal of Medicine, Vol. 340, No. 9, March 4, 1999 (contained in district court record); Minority Staff Report, *Prescription Drug Pricing in the 1st Congressional District of Maine: Drug Companies Profit at the Expense of Older Americans,* Committee on Government Reform and

Oversight, U.S. House of Representatives, prepared for Rep. Thomas H. Allen, October 9, 1998 (same).[8]

Thus, we disagree with the district court's statement that "If Maine can use its authority over Medicaid authorization to leverage drug manufacturer rebates for the benefit of uninsured citizens, then it can just as easily put the rebates into a state program for highway and bridge construction or school funding." Neither highway construction nor school funding relate in any way to the purposes of providing medical services to the needy, *see* 42 U.S.C. § 1396, or of cost effective administration of the Medicaid program, *see id.* § 1396a(a)30(A) (state plans must assure that payments are consistent with, inter alia, efficiency and economy).

PhRMA further contends that the Maine Rx Program will necessarily harm Medicaid recipients by impeding access to their doctors' first-choice medications. The district court agreed with this argument, concluding that the Maine Act conflicted with the Medicaid provision setting forth a general requirement that a state Medicaid plan contain safeguards to assure that care and services will be provided "in a manner consistent with . . . the best interests of the recipients." 42 U.S.C. § 1396a(a)(19). PhRMA vigorously presses the argument that the prior authorization provision is more than a *de minimus* obstacle to achieving these best interests of the Medicaid recipient because it will effectively require a doctor to shift to her second choice drug where the first choice drug is manufactured by a

[8] Moreover, the Amicus Curiae Brief of Viola Quirion, Michelle Campbell, Maine Council of Senior Citizens and Richard Donahue, M. D. attaches an affidavit from Maine resident Viola Quirion indicating that because many older persons cannot afford the high costs of prescription drugs, there may be increased enrollment in nursing homes and an increased burden on Medicaid.

company that does not participate in the rebate program. The state concedes that it will not authorize payment for the first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant, but insists that the Medicaid recipient will always receive medically necessary drugs. At this point in the proceedings, we find insufficient basis for concluding that the Maine Act, on its face, controverts the Medicaid goal of "best interests."

Because this is a facial challenge to a statute, PhRMA has a difficult burden of showing that Medicaid recipients will be harmed by the Maine Rx Program. "A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *United v. Salerno,* 481 U.S. 739, 745 (1987). "The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute." *Rice v. Norman Williams Co.,* 458 U.S. 654, 659 (1982).

Here, the parties submitted competing affidavits discussing whether the Maine Rx Program will necessarily inflict harm on Medicaid patients. Dr. Scott Howell, Vice President of National Accounts, Managed Care, SmithKline Beecham Corporation, states that "when used wrongly," prior authorizations hurt medical professionals and patients by adding administrative burdens, delays, anxiety and confusion. He opines that the Maine Rx Program "will create a high likelihood" of harm by leading to inappropriate prescribing of medications, needlessly burdening doctors, and causing unnecessary inconvenience for Medicaid recipients. "[P]rior authorization of drugs, without regard to safety or efficacy, will lead to drugs being prescribed that are less safe and efficacious."

Dr. Timothy S. Clifford, the Medical Director for the Maine Bureau of Medical Services, which administers the

Medicaid program, disagrees with Dr. Howell's affidavit on several points. He contends that the Department will address safety and efficacy concerns in administering the Maine Rx Program's prior authorization requirement; that it will consider the availability of alternative drugs in deciding whether to subject a particular drug to the requirement; and that Medicaid recipients will continue to have access to medically necessary drugs. Dr. Clifford states: "The Department certainly will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process, regardless of whether the manufacturer participates in the Maine Rx Program . . . ."

Dr. H. Burtt Richardson, Jr., a Maine pediatrician and Maine Medicaid provider, states that he supports the Maine Rx Program "so long as the decision to put a prior authorization on particular drugs is clinically appropriate, feasible for a medical office, and accompanied by the assurance that all Maine Medicaid recipients have access to medically necessary drugs."

These affidavits, along with other materials in the record, fall short of establishing that the Act will inflict inevitable or even probable harm on Medicaid patients or their providers. In reviewing a preemption-based facial challenge, "we do not rest our decision on consequences that, while possible, are by no means predictable." *Dep't of Taxation and Fin. of N.Y. v. Milhelm Attea & Bros., Inc.*, 512 U.S. 61, 69 (1994). There is no evidence that the prior authorization procedure is likely to foreclose a patient from receiving a necessary drug. Although prior authorization review is triggered by a manufacturer's refusal to participate in the Maine Rx Program, the record indicates that the final decision to require prior authorization for a particular drug is based primarily on clinical criteria applied by health care professionals.

Since both sides agree that the prior authorization requirement is the "hammer" or "force" that coerces

manufacturers to enter into the Program, the possibility that first-choice drugs will not be readily approved where second-choice inferior alternatives exist concerns us. The possibility that the administrative implications of the prior authorization requirement will affect the quality of medical care for Medicaid recipients in more subtle ways, i.e. through inconveniencing prescribing physicians, also concerns us. Dr. Howell's affidavit, however, is controverted by the affidavits of other qualified individuals. We simply cannot say on this record that the Act conflicts with Medicaid's requirement that state Medicaid plans assure that care will be provided in a manner consistent with the recipients' best interests. 42 U.S.C. § 1396a(a)(19).

This decision is without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the prior authorization requirement "as applied." *See United States v. Hilton,* 167 F.3d 61, 71 (1st Cir.), *cert. denied*, 528 U.S. 844 (1999) ("It makes little sense to strike down an entire statute in response to a facial attack when potential difficulties can be remedied in future cases through fact-specific as-applied challenges."); *see also Corgain v. Miller,* 708 F.2d 1241, 1251 (7th Cir. 1983) (upholding facial adequacy of plan for prisoner's access to law library, but not foreclosing future challenge to plan as implemented).

D. Dormant Commerce Clause

Holding that the Maine Act is not preempted by the Medicaid statute, we next consider whether it violates the dormant Commerce Clause. The Constitution provides that Congress shall have the power "[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes[.]" U.S Const. art. I, § 8, cl. 3. The constitutional provision affirmatively granting Congress the authority to legislate in the area of interstate commerce "has long been understood, as well, to provide 'protection from

state legislation inimical to the national commerce [even] where Congress has not acted. . . . "" *Nat'l Foreign Trade Council v. Natsios,* 181 F.3d 38, 61 (1st Cir. 1999) (alterations in original) (quoting *Barclays Bank PLC v. Franchise Tax Bd. of Cal.,* 512 U.S. 298, 310 (1994)), *aff'd sub nom. Crosby v. Nat'l Foreign Trade Council,* 530 U.S. 363 (2000). This negative command, known as the dormant Commerce Clause, prohibits states from acting in a manner that burdens the flow of interstate commerce. *Okla. Tax Comm'n v. Jefferson Lines, Inc.,* 514 U.S. 175, 179-80 (1995); *Healy v. Beer Inst.,* 491 U.S. 324, 326 n.1 (1989).

The restriction imposed on states by the dormant Commerce Clause is not absolute, and "the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor,* 477 U.S. 131, 138 (1986) (internal quotation marks omitted). The prohibitions imposed upon state regulation by the dormant Commerce Clause have fallen into several identifiable categories. To determine whether a statute violates the dormant Commerce Clause, we apply one of several levels of analysis, depending on the effect and reach of the legislation.

First, a state statute is a per se violation of the Commerce Clause when it has an "extraterritorial reach." *Healy,* 491 U.S. at 336. "[A] statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id.* When a state statute regulates commerce wholly outside the state's borders or when the statute has a practical effect of controlling conduct outside of the state, the statute will be invalid under the dormant Commerce Clause. *Cotto Waxo Co. v. Williams,* 46 F.3d 790, 793 (8th Cir. 1995) (citing *Healy*). A statute will have an extraterritorial reach if it

"necessarily requires out-of-state commerce to be conducted according to in-state terms." *Id.* at 794.

Second, if a state statute discriminates against interstate commerce, we apply strict scrutiny. It will be scrutinized under a "virtually per se invalid rule," which means that the statute will be invalid unless the state can "show that it advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives." *Or. Waste Sys.. Inc. v. Dep't of Envtl. Quality of Or.,* 511 U.S. 93, 100-01 (1994) (alteration and internal quotation marks omitted). This level of scrutiny will be applied if the state statute discriminates against interstate commerce on its face or in practical effect. *Taylor,* 477 U.S. at 138; *see also Bacchus Imports, Ltd. v. Dias,* 468 U.S. 263, 270 (1984) (indicating that a finding of discriminatory purpose or discriminatory effect can constitute economic protectionism subjecting the state statute to a "stricter level of invalidity"). When a state statute "discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.,* 476 U.S. 573, 579 (1986).

Third, a lower standard of scrutiny is applied when the state statute regulates evenhandedly and has only incidental effects on interstate commerce. In this situation, a balancing test is applied. *Pike v. Bruce Church, Inc.,* 397 U.S. 137, 142 (1970). "Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id.*

PhRMA contends that the Maine Act is an impermissible exercise in extraterritorial regulation and, therefore, is per se violative of the dormant Commerce Clause. It argues that the Act necessarily regulates the

transaction that occurs between the manufacturer and the distributor outside the borders of Maine.

Maine first argues that we need not reach the issue of whether the Act violates the dormant Commerce Clause because it is acting as a "market participant" and is therefore exempt from Commerce Clause restrictions.[9] *See South-Central Timber Dev., Inc. v. Wunnicke,* 467 U.S. 82, 93 (1984) ("if a State is acting as a market participant, rather than as a market regulator, the dormant Commerce Clause places no limitation on its activities"). We hold that Maine does not fall under the market participant exception to the dormant Commerce Clause. Maine is not a market buyer of prescription drugs, except as required by the Medicaid statute. Its citizens will continue to directly purchase prescription drugs as needed. Nothing in the Act makes Maine a market participant.

Maine alternatively argues that the Act evenhandedly regulates in-state conduct that only has an incidental effect on interstate commerce. Maine contends that we should apply the lower level of scrutiny, use the *Pike* balancing test, and find that the local benefits of the Maine Rx Program outweigh the incidental burden on interstate commerce.

The Maine Act represents a novel legislative approach to one of the serious problems of our time, one that resists easy analysis. We address each of the potentially applicable dormant Commerce Clause prohibitions to determine the appropriate analysis and level of scrutiny.

1. Per Se Invalidity: Extraterritorial Reach

A state may not pass laws that have the "practical effect" of regulating commerce occurring wholly outside

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[9] *See* Judge Lynch's opinion in *Nat'l Foreign Trade Council,* 181 F.3d at 62-65, for a thorough scholarly discussion of a state as a market participant.

that State's borders . . . ." *Healy,* 491 U.S. at 332. When evaluating the practical effect of the statute, the court should consider the statute itself, and "how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." *Id.* at 336.

PhRMA relies on three cases to support its argument that the Maine Act is per se invalid because it regulates conduct beyond the borders of Maine. The cases cited, however, are inapposite to the facial construction of the Maine Act. PhRMA construes these cases as standing for the proposition that, "a state may not dictate the terms on which buyers and sellers do business outside of the state." *See, e.g., Healy,* 491 U.S. at 338; *Brown-Forman,* 476 U.S. at 583-84. This is partially correct but does not reflect the entire picture. The cases on which PhRMA relies, however, involve price control, price affirmation or price tying schemes. *See Healy,* 491 U.S. at 326; *Brown-Forman,* 476 U.S. at 575-76; *Baldwin v. G.A.F. Seelig,* 294 U.S. 511, 519 (1935) ("*Seelig*"). The statutes in these cases involved regulating the prices charged in the home state and those charged in other states in order to benefit the buyers and sellers in the home state, resulting in a direct burden on the buyers and sellers in the other states.

In *Healy*, the Court struck down a Connecticut Liquor Control Act that required out-of-state shippers of beer to affirm that the prices at which the products were sold to Connecticut wholesalers were no higher than prices at which those same products were sold in bordering states. 491 U.S. at 326. The Court held the statute to be unconstitutional because it controlled prices in neighboring states and interfered with the regulatory schemes in those states. *Id.* at 338-39.

In *Brown-Forman,* the Court struck down a provision of the New York Alcoholic Beverage Control Law that required liquor distillers to affirm that their prices were no

higher than the lowest price at which the same product would be sold in any other state during the month. 476 U.S. at 575-76. The Court determined that this was an extraterritorial reach violative of the Constitution. It held that "[o]nce a distiller has posted prices in New York, it is not free to change its prices elsewhere in the United States during the relevant month. Forcing a merchant to seek regulatory approval in one State before undertaking a transaction in another directly regulates interstate commerce." *Id.* at 582 (footnote omitted).

In *Seelig,* the Court struck down the New York Milk Control Act, which set minimum prices for milk purchased from in-state and out-of-state producers and banned the resale of milk in New York when that milk had been purchased out-of-state for a lower price. 294 U.S. at 519. By requiring New York wholesalers to buy out-of-state milk at certain prices, the effect of the statute was to essentially set out-of-state milk prices. The Court recognized that the Commerce Clause does not permit a state to create a "scale of prices for use in other states, and to bar the sale of products . . . unless the scale has been observed." *Id.* at 528.

The Maine Act is different from these statutes. Unlike these price affirmation and price control statutes, the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price.[10] Similarly, Maine is not tying the price of its in-state products to out-of-state prices. There is nothing within the Act that requires the rebate to be a certain amount dependent on the price of prescription drugs in other states. The Act merely says that the Commissioner of the Maine Department of Human

[10] As noted above, *supra* fn.2, the anti-profiteering provision of the Act was held unconstitutional and is not part of this appeal.

Services shall use "best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program . . . ." Me. Rev. Stat. Ann. tit. 22, § 2681(4)(B). Furthermore, unlike *Brown-Forman* and *Seelig,* the Maine Act does not impose direct controls on a transaction that occurs wholly out-of-state.

PhRMA argues strenuously that the effect of the Act will be to regulate the transaction that occurs between the manufacturer and the wholesaler -- a transaction that occurs entirely out of state. It argues that as a result of the rebate provision, manufacturers will lose a portion of their profits otherwise obtained from distributors. Admittedly, it is possible that the rebate provisions of the statute may decrease the profits of manufacturers. Simply because the manufacturers' profits might be negatively affected by the Maine Act, however, does not necessarily mean that the Maine Act is regulating those profits.

The Act does not regulate the transaction between manufacturers and wholesalers. It provides for a negotiated rebate agreement between "[a] drug manufacturer or labeler that sells prescription drugs in [Maine] through the elderly low-cost drug program . . . or any other publicly supported pharmaceutical assistance program . . . ." Me. Rev. Stat. Ann. tit. 22, § 2681(3). The rebate program is voluntary and either the manufacturer or the State may withdraw at any time with sixty days' notice. The Act directs the commissioner to "use the commissioner's best efforts" to negotiate the amount of the rebate required from the manufacturer. *Id.* § 2681(4)(B). We note that the commissioner's "best efforts" may become coercive or otherwise inappropriate, but we cannot say so on this facial challenge. This may be an issue that needs to be revisited once the Act takes effect. On a facial challenge, however, the use of the commissioner's "best efforts" indicates that the Act is not "regulating" prices, but merely "negotiating" rebates.

The Act clearly does not interfere with regulatory schemes in other states. Ultimately, the Maine Act simply regulates activity that occurs in state: (1) the purchase of the prescription drugs that triggers the rebate; (2) the negotiation of a rebate amount; and (3) the State's action subjecting a manufacturer's drug to prior authorization and releasing the manufacturer's name to health care providers and the public occurs in state. Because the regulation only applies to in-state activities, there is no extraterritorial reach and the Act is not per se invalid under the Commerce Clause.

One final consideration is the consequence of other states passing similar statutes. *See Healy*, 491 U.S. at 336 (considering "what effect would arise if not one, but many or every, State adopted similar legislation"). The most apparent effect of similar statutes being passed in other states would be a loss in profits for manufacturers. It does not appear, and PhRMA does not argue, that statutes similar to the Maine Act, if enacted, would result in manufacturers having inconsistent obligations to states, or in creating a "price gridlock" linking prices in some states to the prices in other states. *See Healy*, 491 U.S. at 340. Therefore, at this time, when we are dealing with a facial challenge to the Act, there is no evidence that adverse effects on interstate commerce will occur if such legislation were passed in other states. The Act is not per se violative of the Commerce Clause.

2. Strict Level of Scrutiny: Discriminatory Statute

A statute enacted for a discriminatory purpose is subject to strict scrutiny. *See Bacchus Imports, Ltd.*, 468 U.S. at 270. Under this strict scrutiny analysis, a statute violates the Commerce Clause unless the state can show that the statute serves a legitimate local purpose that is unrelated to economic protectionism and that the same purpose could not be achieved by nondiscriminatory means. *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979). PhRMA does not

contend, nor did the district court find, that the Maine Act discriminates on its face or in its effects. Therefore, we need not discuss it further.

3. Low Level of Scrutiny: Pike Balancing Test

When a state statute regulates evenhandedly and has only incidental effects on interstate commerce, that statute will be upheld unless the burden on interstate commerce is "clearly excessive in relation to the putative local benefits." *Pike*, 397 U.S. at 142.

> Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities. Occasionally the Court has candidly undertaken a balancing approach in resolving these issues, but more frequently it has spoken in terms of "direct" and "indirect" effects and burdens.

Id. (internal citations omitted). The Maine Act is neither an impermissible extraterritorial reach nor is it discriminatory; rather, it regulates evenhandedly and only has incidental effects on interstate commerce. Therefore, we apply this lower level of scrutiny, known as the *Pike* balancing test.

The district court found the Maine Act to be per se invalid, and therefore never determined whether it survives the *Pike* balancing test. Though the district court did not undertake such an analysis, we may conduct the *Pike* balancing test for the first time on appeal. *See Instructional*

Sys., Inc. v. Computer Curriculum Corp., 35 F.3d 813, 826 (3d Cir. 1994). In *Instructional Systems*, the Third Circuit considered a facial challenge to the New Jersey Franchise Practices Act after the district court had declared the statute per se invalid under the dormant Commerce Clause. *Id.* at 826. The court found that the statute, from a facial standpoint, survived the *Pike* test, and reversed the district court judgment which had declared the statute unconstitutional. *Id.* at 827. The Third Circuit recognized, however, that the issue of whether the statute, when applied, burdens interstate commerce could not be resolved as a matter of law. *Id.*

Applying the *Pike* balancing test to the Maine Act, we consider: (1) the nature of the putative local benefits advanced by the statute; (2) the burden the statute places on interstate commerce; and (3) whether the burden is "clearly excessive" as compared to the putative local benefits. *See Pike*, 397 U.S. at 142.

Arguably, the only burden imposed on interstate commerce by the Maine Act is its possible effects on the profits of the individual manufacturers. As the Third Circuit stated, however, "the fact that a law may have 'devastating economic consequences' on a particular interstate firm is not sufficient to rise to a Commerce Clause burden." *Instructional Sys.*, 35 F.3d at 827 (quoting *Ford Motor Co. v. Ins. Comm'r*, 874 F.2d 926, 943 (3d Cir. 1989)); *see also Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127-28 (1978) (stating that "the [Commerce] Clause protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations.").

We next consider the local benefits of the Act, which we find to be substantial. The Maine Rx Program will potentially provide prescription drugs to Maine citizens who could not otherwise afford them. The Maine Legislature has decided that without the Maine Rx Program, needy Maine citizens will continue to be deprived of necessary medical

care because of rising prescription drug costs. When measuring manufacturers' possible loss of profits against the increased access to prescription drugs for Maine citizens, the local benefits appear to outweigh the burden on interstate commerce. At the very least, the burden on interstate commerce is not "clearly excessive" as compared to the local benefits.

It is necessary to recognize the difficulty in foreseeing what events actually will occur from the enforcement of this Act, which admittedly makes the *Pike* balancing test more challenging to apply. We are forced to balance the *possible* effects, instead of the *actual* effects of the statute in action. For now, it is enough to say that the Act survives the facial challenge under the dormant Commerce Clause.[11]

E. Remaining Preliminary Injunction Factors

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[11] On appeal, Maine argues in the alternative that the Act does not violate the dormant Commerce Clause because if the rebate provision of the Act is construed as a tax, it satisfies the requirements set forth in the *Complete Auto* line of cases dealing with taxation on interstate commerce. *See Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274, 279 (1977) (holding that a state's tax on interstate commerce will be upheld only if it "is applied to an activity with a substantial nexus with the taxing State, is fairly apportioned, does not discriminate against interstate commerce, and is fairly related to the services provided by the State."). PhRMA replies, arguing that the *Complete Auto* test is not satisfied. We need not address this argument on the merits, however, because this legal theory was not raised before the district court. "'If any principle is settled in this circuit, it is that, absent the most extraordinary circumstances, legal theories not raised squarely in the lower court cannot be broached for the first time on appeal.'" *Boateng v. Interamerican Univ., Inc.*, 210 F.3d 56, 62 (1st Cir. 2000) (quoting *Teamsters Union, Local No. 59 v. Superline Transp. Co.*, 953 F.2d 17, 21 (1st Cir. 1992)). This is not one of those extraordinary circumstances.

Having concluded that PhRMA is not likely to succeed on the merits of its constitutional challenges, we need not delve into the three remaining preliminary injunction factors (risk of irreparable harm, the balance of equities and the public interest). This court has recognized that the "sine qua non" of the preliminary injunction analysis is whether the plaintiff is likely to succeed on the merits of the claim. *Weaver v. Henderson,* 984 F.2d 11, 12, 14 n.5 (1st Cir. 1993) (concluding that, after determining that there was no likelihood of success on the merits, it was not necessary to examine the other factors). We must conclude that PhRMA has not satisfied its burden to obtain a preliminary injunction preventing the implementation of the Act.

III. CONCLUSION

In this facial challenge, we perceive no conflict between the Maine Act and the Medicaid statute that would result in federal preemption. The Act sets forth prior authorization procedures that are consistent with those explicitly permitted by Medicaid. PhRMA has not established at this point that the administrative burden imposed by prior authorization will likely harm Medicaid recipients. In the absence of such evidence, we cannot conclude that the Act violates the Supremacy Clause.

Nor does the Act offend the dormant Commerce Clause. It is not an extraterritorial regulation on interstate commerce because it does not regulate conduct occurring outside the state, but only regulates in-state activities. Moreover, from a facial standpoint, the local benefits of the Act appear to outweigh any incidental burden on interstate commerce. For the reasons stated, the Maine Act survives the facial dormant Commerce Clause challenge.

This is a close case but we do not think that, under the applicable law, the State of Maine should be prohibited from putting the Act into play. We heed the dissent of Justice

Louis Brandeis in *New State Ice Co. v. Liebmann,* 285 U.S. 262, 310 (1932):

> To stay experimentation in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation. It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country. This Court has the power to prevent an experiment. We may strike down the statute which embodies it on the ground that, in our opinion, the measure is arbitrary, capricious, or unreasonable. We have power to do this, because the due process clause has been held by the Court applicable to matters of substantive law as well as to matters of procedure. But, in the exercise of this high power, we must be ever on our guard, lest we erect our prejudices into legal principles. If we would guide by the light of reason, we must let our minds be bold.

(footnote omitted).

The decision of the district court is REVERSED and the temporary injunction is VACATED.

- Concurring Opinion Follows -

APPENDIX

The relevant provisions of the Act are as follows:

> The Maine Rx Program, referred to in this subchapter as the "program," is established to reduce prescription drug prices for residents of the

State. The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a pharmacy benefit manager in establishing rebates and discounts on behalf of qualified residents.

1. Program goals. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare. It is not the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter.

* * * *

3. Rebate agreement. A drug manufacturer or labeler that sells prescription drugs in this State through the elderly low-cost drug program under section 254 or any other publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program. The rebate agreement must require the manufacturer or labeler to make rebate payments to the State each calendar quarter or according to a schedule established by the department.

4. Rebate amount. The commissioner shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

A. The commissioner shall take into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs and any other information on prescription drug prices and price discounts.

B. The commissioner shall use the commissioner's best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.

KEETON, *District Judge* (concurring).

I. Introduction

I concur in the judgment reversing the decision of the district court and vacating the preliminary injunction. Because the appropriate grounds of the decision involve issues that are fundamental to harmonizing interests in liberty and order under the Constitution of the United States, I conclude that it is appropriate, if not obligatory, that I state in a concurring opinion the grounds as I see them for reaching this judgment.

For reasons associated with undisputed facts about Pharmaceutical Benefit Managers (PBMs) and relationships between interests they represent and interests of citizens of Maine represented by the Commissioner, Maine Department of Human Services, Maine's Legislature, and Maine's Attorney General, I turn first to a more extended recitation of background facts regarding standing and jurisdiction than

appears in the opinion of the Court of Appeals, delivered by Judge Bownes.

II. Background Facts on Standing and Jurisdiction to Consider Group or Association Contentions

Did the district court have authority, and does the Court of Appeals have authority, to consider positions stated in briefs on behalf of groups or associations seeking to represent the interests of their members that they claim are materially affected by orders made, or that might be made, in the district court and on appeal?

The case before us is styled Pharmaceutical Research and Manufacturers of America, Plaintiff, Appellee, v. Kevin Concannon, Commissioner, Maine Department of Human Services, and Maine Attorney General, Defendants, Appellants.

Plaintiff/Appellee's CORPORATE DISCLOSURE STATEMENT says that "plaintiff/appellee, Pharmaceutical Research and Manufacturers of America, by and through its undersigned counsel, and, pursuant to Fed. R. Civ. P. 26.1, states that it has no parent company and that no publicly held company owns any of its stock."

In its brief, which uses the short title PhRMA to designate itself, Plaintiff/Appellee refers to additional characteristics and rights of PhRMA.

+ It has the ability to challenge adverse treatment under the Maine Act, including a challenge on preemption grounds. Plaintiff/Appellee's Brief at 34.
+ It has members who are "regulated by and make payments consistent with the provisions of the Medicaid prescription drug program." *Id.* at 36 n.21.

Also, on the basis of the limited information available in the record, I infer that some of PhRMA's members are

Pharmacy Benefit Managers (PBMs). No party or amicus, or attorney for a party or amicus, has called attention to any case explicitly declaring that PBMs have standing and a United States district court has jurisdiction to consider either a facial challenge or an as-applied challenge by a PBM to a state statute like Maine's Act to Establish Fairer Pricing for Prescription Drugs, and I am aware of none. Treating the issue as one of first impression, I would recognize both standing and jurisdiction, in the United States District Court for the District of Maine, and on appeal. In the world outside the court system, as a pragmatic matter no other person or entity is as active and effective in protecting benefits and beneficiaries of availability of pharmacy products at reasonable cost as PBMs. It is entirely appropriate in these circumstances that the standing of PBMs be recognized in United States district courts and on appeal from adjudications interpreting and applying state legislation affecting the benefits and interests of beneficiaries of marketing of pharmacy products. As the Court of Appeals for the First Circuit has previously stated, "Article III standing is largely . . . albeit not entirely . . . a practical jurisprudence." *New Hampshire Hemp Council v. Marshall,* 203 F.3d 1, 4 (1st Cir. 2000) (citing 13 Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice and Procedure §3531.1, at 352, 362-63 (2d ed. 1984)).

The basis for the foregoing conclusions is a principled proposition that applies broadly. I state explicitly, for the sake of clarity, that in my view it applies to each of the following contentions, in addition to the standing of PhRMA and the standing of PBMs to make the contention stated above:

(A) claims of violation of the Supremacy Clause;

(B) claims of violation of Dormant Commerce Clause jurisprudence (as to which, with respect to PhRMA's

standing, see also Part 1I. D of opinion of the Court of Appeals, delivered by Judge Bownes).

For the reasons explained in the remainder of this opinion concurring in the judgment, I would allow standing and jurisdiction but reject on the merits other specific challenges to the Maine Rx Program.

III. Madisonian Influences on Allocation of Legislative Power in the American Legal System

The roles of state legislatures and the Congress of the United States in the American legal system owe much to James Madison's seminal thinking expressed publicly and privately during debates over the structure of the new form of federalism to be established under a constitution drafted in May, 1787 to cure deficiencies in the Articles of Confederation of 1777. *See generally* John P. Kaminski, Ph.D., Director, and Richard Leffler, Ph.D., Co-Director, The Center for Study of the American Constitution, The University of Wisconsin-Madison (Wisconsin Study), *The Origins of the Three Branches of Government,* Federal Judicial Center Traveling Seminar 3-9 (2001).

Madison, a Virginian, writing to Edmund Randolph of New York on 8 April 1787, mused:

> I hold it for a fundamental point that an individual independence of the States, is utterly irreconcilable with the idea of an aggregate sovereignty. I think at the same time that a consolidation of the States into one simple republic is not less unattainable than it would be inexpedient. Let it be tried then whether any middle ground can be taken which will at once support a due supremacy of the national authority, and leave in force the local authorities so far as they can be subordinately useful.
>
> * * * *

> Let the national Government be armed with a positive & compleat authority in all cases where uniform measures are necessary. As in trade &c. &c. Let it also retain the powers which it now possesses.
>
> Let it have a negative in all cases whatsoever on the Legislative Acts of the States as the K. of G. B. heretofore had. This I conceive to be essential and the least possible abridgement of the State Soveriegnties. Without such a defensive power, every positive power that can be given on paper will be unavailing. . . .
>
> Let this national supremacy be extended also to the Judiciary departmt. If the judges in the last resort depend on the States & are bound by their oaths to them and not to the Union, the intention of the law and the interests of the nation may be defeated by the obsequiousness of the Tribunals to the policy or prejudices of the States. It seems at least essential that an appeal should lie to some national tribunals on all cases which concern foreigners, or inhabitants of other States. . . .
>
> The supremacy of the whole in the Executive department seems liable to some difficulty. Perhaps an extension of it to the case of the Militia may be necessary and sufficient.
>
> A Government formed of such extensive powers ought to be well organized. . . .
>
> * * * *
>
> To give the new system its proper energy it will be desirable to have it ratified by the authority of the people, and not merely by that of the Legislatures.

The Origins of the Three Branches of Government, id., at 4-5. Madison concluded these thoughts with a statement that,

fearing "you will think this project, if not extravagant, absolutely unattainable and unworthy of being attempted," he conceived it "to go no further than is essential." *Id.* at 6.

In his Notes of Convention Debates, Madison records Resolutions proposed by Mr. Randolph in Convention on May 29, 1787, including a set of proposals for a form of federalism remarkably similar to Madison's suggestions six weeks earlier.

Those Madisonian suggestions are reminders of two salient points relevant to our consideration of the issues presented in the present appeal.

First. The genius of the Constitution of the United States of America is that it establishes a unique form of federalism, unlike any ever fashioned before, that harmonizes and accommodates in new and distinctive ways national and state centers of governmental power.

Second. The authority for this new form of federalism is declared by "the people, and not merely by the Legislatures." *See id* at 5.

The eighteenth-century debates in which Madison and Randolph were among the key participants occurred more than two centuries ago. Twenty-first century readers are even more removed than the lapse of time suggests from being in tune with the spirit and culture surrounding the debates over what became the Constitution of the United States and the Bill of Rights embodied in the Amendments adopted forthwith. Those debates were strikingly lively and thorough examinations of the history of peoples' ideas and efforts to form governments powerful enough to preserve the order essential to protection of individual liberty and at the same time subject to inherent controls against abuse of power likely to lead to despotism.

Ideas about liberty and order are no less relevant now than they were when the Founders developed the Constitution of the United States of America. "The aim of

the American legal system is liberty and justice for all. How close we come to that aim depends on good judging." Robert E. Keeton, *Judging in the American Legal System* 1 (Lexis Law Publishing 1999).

> The quality of judging in a legal system depends on commitment. It depends, first, on commitment to the aim of justice. Second, it depends on commitment to professionalism. The declared beliefs of all professionals in the system - including advocates, counselors, and academic critics as well as judges -affect the quality of judging in the system. Third, the quality of judging depends on commitment to method. Judicial choice, at its best, is reasoned choice, candidly explained.

Id. at 5. Reasoned judicial choice in the matter currently pending before us requires, in my view, that we reject plaintiff's facial challenge to the constitutionality of the Maine statute, but does not require that we consider the constitutionality of every possible interpretation or application of the Maine statute. This view is reinforced by taking into account James Madison's contributions to federalist thought and actions. This historical background is especially relevant, in my view, to disputes over supremacy of national legislation and associated issues of interpretation of the Maine statute that was before the district court and is before us in this appeal.

IV. In the American Legal System, a State is a Sovereign

Under fundamental premises of the American legal system, the State of Maine, like all other States of the United States of America, is a sovereign. Each State has authority to govern persons and institutions and their transactions within its territorial boundaries.

I do not understand that any of the briefs before us challenges the sovereignty of states within the Union, and I

do not understand the opinion of the Court of Appeals as challenging this proposition. Thus, I say no more here on the existence of sovereignty of states within the Union. Some important implications of this sovereignty, however, are noted in other sections of this opinion, *infra*.

V. A State May Act in Multiple Roles

A sovereign State of the United States, in addition to governing, may be an active participant in a market for any kind of goods or services that it seeks to buy for its own use, including a purchase for (1) a use such as obtaining furniture for a State office and (2) a use such as obtaining pharmacy products for State-sponsored programs such as Medicaid and Medicare.

Thus, the State of Maine may act

(1) as a sovereign,

(2) as a market participant itself because it buys pharmacy products for Medicaid patients, and

(3) in "the role of each State as a guardian and trustee for its people" who need pharmacy products at affordable prices. *White v. Massachusetts Council of Constr. Employers,* 460 U.S. 204, 207 n.3 (1983).

The third of these roles has special relevance to issues in this case because Maine has undertaken to represent "its people" who need pharmacy products at affordable prices.

It would be a curious irony indeed if dozens of privately organized groups of Pharmacy Benefit Managers (PBMs) could participate freely in the market for purchasing products from pharmacy product manufacturers but States as guardians and trustees for their people could not because the States are also sovereign. In my view, we should make the commonsense ruling that the State of Maine as well as PBMs may participate in the market for purchasing pharmacy products.

Any conflict of interest problems that might theoretically be raised are answered in the distinctive circumstances of this case by the fact that the State of Maine faces no conflicting interests because it believes that in all its roles it is trying to serve the best interests of its people and each of the groups of its people who have an interest in and need for pharmacy products.

VI. Interpreting "Best Efforts" Provisions of the Maine Statute

A. The Statutory Maine Rx Program

By a legislative enactment in the first quarter of the year 2000, the State of Maine established The Maine Rx Program ("the program"). Maine's Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) ("The Act"). The Act established the program "to reduce prescription drug prices for residents of the State." *Id.,* Me. Rev. Stat. Ann. tit. 22, § 2681 (unnumbered introductory paragraph).

> The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a *pharmacy benefit manager* in establishing rebates and discounts on behalf of qualified residents.

Id. (emphasis added).

> The legislation was explicit in declaring program goals.
>
> 1. Program goals. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature to enable the State to act as a *pharmacy benefit manager* in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare. It is not

the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter.

Me. Rev. Stat. Ann. tit. 22, § 2681 (emphasis added).

Some of the statutory definitions of terms are relevant to interpretive issues before us in this appeal.

> 2. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.
>
> * * * *
>
> B. "Initial discounted price" means a price that is less than or equal to the average wholesale price, minus 6%, plus the dispensing fee provided under the Medicaid program under this Title.
>
> * * * *
>
> E. "Pharmacy benefit manager" means an entity that procures prescription drugs at a negotiated rate under a contract.
>
> * * * *
>
> G. "Secondary discounted price" means a price that is equal to or less than the initial discounted price minus the amount of any rebate paid by the State to the participating retail pharmacy.

Id.

Also relevant to the matters before us are the statutory provisions on rebate amount.

> 4. Rebate amount. The commissioner shall *negotiate* the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

> * * * *
>
> B. The commissioner *shall* use the commissioner's *best efforts* to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.
>
> C. With respect to the rebate taking effect no later than October 1, 2001, the commissioner shall use the commissioner's *best efforts* to obtain an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government.

Id. (emphasis added).

Finally, statutory provisions on discounted prices for qualified residents, in subsection 5, are relevant to the matters before us.

> B. Beginning January 1, 2001, a participating retail pharmacy shall offer the initial discounted price.
>
> C. No later than October 1, 2001, a participating retail pharmacy shall offer the secondary discounted price.

Id.

B. Statutory Interpretation

We should be guided primarily by the plain language of all the provisions of the statute that are relevant to the issues before us, and the plain and ordinary meaning of the words used in all the relevant provisions. The relevant provisions include the definitions in the statute, the declaration of program goals, and the operational directives to Defendant/Appellant Kevin Concannon, Commissioner, Maine Department of Human Services. With these guideposts in mind, I conclude that a reasonable interpretation of the Maine statute includes the following elements:

+ The Maine statute authorizes "best efforts" of Maine administrators rather than requiring prohibitive administrative decisions and actions.
+ The courts should respect the legislative drafters' thoughtful use of the idea of "best efforts."
+ It would be a mistake to accept the suggestions of challenges to the Maine statute that propose to interpret it in a way that, in effect, reads "best efforts" out of the statute.

The provision that opponents describe as requiring authorization for participating pharmacies to offer discounted prices to some defined group of Maine residents and obtain rebates from a state fund, created by an assessment against manufacturers, is *not* a statutory mandate. Instead, the statute requires only "best efforts" of Administrators to achieve the legislative aim of protecting interests of the people of Maine by ongoing creative mediation and negotiation that appeals to the executives of pharmacy products manufacturers to cooperate with Maine's administration of legislatively authorized programs. The statutory provisions providing for "best efforts" and for "negotiation" make clear that the drafters intended the rebate process to entail negotiation and compromise between the state and the manufacturers to reach a mutually beneficial outcome. Although conceivably these "best efforts" could fail, and manufacturers could be subject to the prior authorization provisions of the statute, this outcome is not mandated by the language of the statute, and it is not necessary, in a facial challenge to the statute, to reach questions that may be presented in the future if "best efforts" fail.

As a practical matter, it is obvious that many, probably most, citizens of Maine who have a need for pharmacy products but have less than the economic resources of, say, the top ten percent of citizens of the state, do not have

adequate resources and practical means to get the pharmacy products they need unless

(i) by travel to Canada, or

(ii) by mail, or

(iii) in some other way that involves aid or assistance comparable to that PBMs provide.

If these citizens have a need for prescription medication, and choose to forgo that medication rather than resort to these resources, it may well be in the interests of PhRMA members to negotiate with the State of Maine. In light of allegations made in their submissions, I infer that PhRMA members believe that a rebate in the amount of the Medicaid rebate would not be in their best interest, but the plain language of the statute allows for negotiation in a way that will serve the best interests of both PhRMA members and previously unrepresented citizens of the State of Maine.

VII. The Timing of Adjudications on Constitutionality

The Maine statute, interpreted in the way explained in Part VI, is consistent with all State and Federal constitutional doctrines and is permissible legislation. The district court's ruling to the contrary must be vacated. No federal law (constitutional, statutory, or decisional) preempts and thus forbids reasonable implementation of Me. Rev. Stat. Ann. tit. 22, § 2681.

Properly interpreted, that law is compatible with rather than conflicting with federal Medicaid legislation and administrative supervision of Medicaid.

It is error to say -- as is said in Defendants/Appellants' Brief at page 18 -- that the extent to which the Act advances the purposes of Medicaid is irrelevant. Also, it is error to say that the "proper question" in this appeal "is whether the Act conflicts with the purposes of Medicaid," as Defendants/Appellants' Brief asserts at page 18. The core

question is multifarious, not singular. An evaluative legal test applies, not a bright-line elements legal test.

Plaintiff/Appellee proposes in its waiver and preclusion arguments that we should hold that the fact that Defendants/Appellants make these fallacious arguments bars relief to Defendants/Appellants in this appeal. I would reject this argument. It does not state a valid reason for depriving the citizens of Maine of a fair adjudication of their interests appeal, based on a proper interpretation of the Maine statute. Our federal system permits a State's advocacy in court in support of its interests and those of its people. Penalizing a state and its people whenever the state makes an argument rejected by the court is not appropriate.

Other arguments presented by Defendants/Appellants both here and in the district court are consistent with the interpretation of the Maine statute explained in Part VI of this opinion and support reversal of the judgment of the district court.

An unstated but implicit premise of Plaintiff/Appellee's position in this case is that all Plaintiff/Appellee need do to succeed in a facial challenge to the Maine Act is to show that the administration of the Act is putting pressure on Plaintiff/Appellee, thus making its choice about how it responds to the circumstances developing under ongoing administration of the Act not *entirely* voluntary.

The fallacy of that position stems from the fact that few choices of individuals and entities in a geographical territory that has a government are *entirely* voluntary. True, some transactions are beyond governmental authority to intrude. They are "transactions beyond law" in the sense that individuals and private (non-governmental) entities they create and maintain have a large range of freedom under law to do as they please without governmental intrusion on that freedom. But a demand by any individual or entity for entire freedom is fundamentally in conflict with having a

government that maintains the order essential to protection of individual freedom.

It is possible, as explained in Part VIII, *infra*, to fashion remedies for any threats that may arise from overstepping the bounds of statutorily authorized "best efforts" of Maine's Commissioner of Human Services during the ongoing administration of the Maine Rx Program. It is appropriate to wait and see what happens, and fashion appropriate remedies for any overstepping, rather than declaring Maine's Act unconstitutional because of an outside chance that something beyond constitutional bounds will be attempted unless an advance declaration of facial invalidity of the statute by the district court is allowed to stand.

VIII. Remedies for Threats to Overstep Statutory Authorization

A United States district court, confronted with a facial challenge to validity of a state statute on grounds like those asserted in this case, should dismiss the facial challenge for failure to meet the requirements of applicable precedents.

The court might also find it appropriate to declare explicitly that the dismissal on this ground would not be a bar to an otherwise properly supported claim for relief against a threatened administrative overstepping of the bounds of the statutory authorization for administrative "best efforts" to negotiate and implement a suitable accommodation of legitimate interests by methods acceptable to Maine's Commissioner of Human Services, acting both for the State and as a PBM for its people, and to manufacturers of pharmacy products who wish to market their products in Maine consistently with the Maine Rx Program.

The decision would be one to wait and see, and act then if needed, instead of prohibiting legislatively sponsored administrative aid to the people of Maine because of a

possibility that at some time in the future some administrator will overstep the bounds of the legislative authorization.

For example, acting under this wait-and-see principle, the Court of Appeals would vacate the District Court's preliminary injunction, but at the same time declare that its ruling would not stand as a bar to renewed proceedings in the District Court if at some future time the Legislative or Executive Branch of the sovereign State of Maine, or an Administrative Agency authorized to act to serve the declared legislative aim of the statute in issue, takes action that is an imminent threat to legally protected interests of a person or entity (including any out-of-state as well as any in-state person or entity) claiming a right to market pharmacy products in Maine. An as-applied challenge to state legislation is a more flexible instrument of adjudication, more capable of reaching an outcome tailored to the circumstances and needs of a case at hand than the all-or-nothing nature of a facial challenge to validity.

A federal district or appellate court's acting in advance of overstepping, because of the possibility overstepping might occur in the future, is fundamentally inconsistent with the body of precedents establishing the elements of a successful facial challenge in a federal court to the consistency of a state statute with potentially preemptive federal law. *See, e.g., California Coastal Comm'n v. Granite Rock Co.,* 480 U.S. 572, 579-80 (1987) (holding that state permit requirements were not preempted by federal law, and stating that the party arguing in favor of preemption would have to demonstrate "*that there is no possible* set of conditions that the [state] could place on its permit that would not conflict with federal law - that any state permit requirement is *per se* preempted") (underscoring added). These precedents would require PhRMA to "*that there is no possible*" application of the statute that would not conflict with the structure and purpose of Medicaid. PhRMA cannot meet this burden. It could not

do so even if we softened the legal standard a bit by substituting "reasonably likely" for "possible." PhRMA's facial challenge must be denied.

A federal court's acting in advance of overstepping by state officials, and responding to a facial challenge, is also inconsistent with relevant precedents for a facial challenge on constitutional grounds. In *United States v. Salerno,* 481 U.S. 739 (1987), the Supreme Court stated that "a facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *Id.* at 745.

It is true that the *Salerno* decision has been criticized in later opinions of some Justices of the Supreme Court. *See, e.g., Washington v. Glucksberg,* 521 U.S. 702, 740 (1997) (Stevens, J., concurring in the judgments) (declaring that the Court has never in fact applied "such a strict standard."); *Janklow v. Planned Parenthood,* 517 U.S. 1174, 1175-76 (1996) (Stevens, J., respecting the denial of the petition for certiorari) (calling the *Salerno* decision "draconian" and declaring that it "does not accurately characterize the standard for deciding facial challenges.").

Salerno, nevertheless, continues to be cited by both the Supreme Court and the Courts of Appeals. *See, e.g., Anderson v. Edwards,* 514 U.S. 143, 155 n.6 (1995); *Reno v. Flores,* 507 U.S. 292, 301 (1993); *Rust v. Sullivan,* 500 U.S. 173, 183 (1991). We need not reach the issue of the applicability of the *Salerno* test, however, because the statute in this case, as explained in Part VI of this opinion, is capable of an interpretation and an application that is respectful of limits imposed by the Constitution.

The application of facial-challenge jurisprudence in the circumstance of this case before the District Court and in this appeal is, in practical effect, a considerable stretch beyond any thus-far-successful facial challenge. If such an

extension of the jurisprudence of facial challenges expressed in decisions of the Supreme Court of the United States is to occur, it is more appropriate that it occur in an opinion of that Court than in an opinion of a Court of Appeals.

My own reading of the array of Supreme Court opinions on this subject, even in light of the ongoing differences both within the Court and among scholars on the applicability of the *Salerno* test, is that precedent points away from rather than toward softening in any way the rigorous requirements for presenting a successful facial challenge to validity of a state statute.

This conclusion is supported not only by the opinions explicitly reasoned as part of the facial-challenge jurisprudence but also by other ongoing developments of federal law.

One ongoing development supportive of the conclusion I propose is the resurgence in recent years of emphasis on the respect that inferior federal courts are directed to show for the freedom of the people of a locality and local governmental institutions to make their own decisions. For illustrative citations, *see* Part IX of this opinion, *infra*. *See also* the Madisonian principles identified in Part III, *supra*. This emphasis is in part a feature of the distinctive version of federalism underlying what is commonly called the American legal system. It is associated with the Supreme Court's invoking the Commerce Clause not for the ordinary purpose of sustaining federal legislation but to strike down state legislation. This emphasis on federalism weighs in favor of sustaining rather than striking down the Maine Rx Program, as explained in Part IX, *infra*.

IX. The Commerce Clause and Concerns of Federalism

The Brief of Washington Legal Foundation and five other associations as Amici Curiae in support of affirming the preliminary injunction ordered by the District Court for the District of Maine argues that the District Court was

correct in "find[ing] that the [Maine Rx] Program violated the Commerce Clause because it attempted to regulate transactions taking place solely outside the State," and in adding, "Maine may have power over what pharmacies later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the price paid in earlier transactions in other states." Brief of Washington Legal Foundation et al. at 6.

A similar position is developed in the Brief Amicus Curiae of the Chamber of Commerce of the United States in Support of Appellee Recommending Affirmance.

> The Commerce Clause [of the United States Constitution] provides that "[t]he Congress shall have Power . . . [t]o regulate Commerce . . . among the several States. . . ." Art. I, § 8, cl. 3. It is long established that, while a literal reading evinces a grant of power to Congress, the Commerce Clause also directly limits the powers of the States. . . . [*Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992) (citing authorities).]

Brief Amicus Curiae of the Chamber of Commerce of the United States in Support of Appellee Recommending Affirmance at 7. The citations relied upon include the following:

> *Healy v. The Beer Institute*, 491 U.S. 324, 336 (1989) ("a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature. The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State."); *see generally* Laurence H. Tribe, American Constitutional Law, §6-12 at 1098 (3d ed. 2000)

(referencing "the *per se* principle against extraterritorial state regulation").

Id. at 9.

These arguments are classic illustrations of the controversial efforts that have occurred from time to time to treat the Commerce Clause not only as authorizing legislation by the Congress of the United States but also as constraining state legislation.

Consider, for example, a case emphasized in the Brief of the Chamber of Commerce, *Wyoming v. Oklahoma,* 502 U.S. 437 (1992). Unlike the case before us, this was a direct clash between two States of the Union. Wyoming, a major coal producing State, though not a seller of coal, imposed a severance tax on those who extracted coal. The direct impact of that severance tax on the price of Wyoming coal purchased by four Oklahoma electric utilities was obvious. The Oklahoma legislature passed an act requiring coal-fired electric utilities in Oklahoma to burn a mixture containing at least 10% Oklahoma-mined coal. The utilities reduced their purchases of Wyoming coal. Wyoming's severance tax revenues declined. Wyoming sought relief under the original jurisdiction of the Supreme Court of the United States. The Court accepted Wyoming's complaint and held the Oklahoma act invalid under the "negative" aspect of the Commerce Clause on the reasoning that it "prohibits economic protectionism - that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Id.* at 454. Even so, the Court added that a clearly discriminatory statute will be struck down "unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism," *citing Maine v. Taylor,* 477 U.S. 131 (1986).

I need not and do not consider whether the case before us would qualify for the exception. Instead, I conclude that

the case before us is not one subject to the "negative" rule itself, quite apart from the exception.

Wyoming v. Oklahoma and other opinions of the Supreme Court that have gone farthest in the direction of a "negative" application of the Commerce Clause do not support the proposition that a federal court acts properly when it disregards all the indicia of the State's purpose in establishing the Maine Rx Program to regulate transactions within the territorial boundaries of Maine and to protect the health of the people of Maine. In these circumstances a federal court does not act properly when it makes a judicial "finding" that the State's declaration of purpose is a facade and the real purpose was "to regulate the price paid in earlier transactions in other states."

First. The legislative aim of the Act was fully stated in the Act itself, as explained in Part V1. A of this opinion, *supra*. This is not a case of hidden or obscure aims.

Second. Any suggestion to the contrary in briefs before this court is in disregard of our obligation, and that of the District Court, in reading the statute, to be guided, as stated in Part V1.B of this opinion, by the plain language of the statute, the definitions in the statute, and the plain and ordinary meaning of the words used in the declaration of program goals, in the statutory definitions, and in the operational directives to Maine's Commissioner of Human Services. *See Whiting v. Town of Westerly,* 942 F.2d 18, 21 n.3 (1st Cir. 1991) ("In evaluating a facial challenge to a state law, a federal court must consider any limiting construction that a state court or enforcement agency has proffered.").

Third. As stated in Part VI. B, the provision of the Maine Act that opponents describe as requiring authorization for participating pharmacies to offer discounted prices to some defined group of Maine residents and obtain rebates from a state fund, created by an

assessment against manufacturers, is not a statutory mandate. Instead, it is a statement of aim. The statute requires only "best efforts" of Administrators to achieve the legislative aim of protecting interests of the people of Maine by ongoing creative mediation and negotiation.

Fourth. As stated in Part VI.B, many and probably most citizens of Maine who have a need for pharmacy products would not have adequate resources and practical means to get the pharmacy products they need absent the Maine Rx Program. In the course of the creative mediation and negotiation required by the statute, the pharmaceutical companies themselves may find it is in their best interests to enter into agreements to allow them to reach this previously untapped market for their products.

Fifth. In view of the foregoing four points, it cannot be proper for a federal court to make judicial "findings" contrary to Maine's legislative declarations and on that basis declare that Maine's Act is invalid because "it attempted to regulate transactions taking place solely outside the State" and attempted "to regulate the price paid in earlier transactions in other states." In so doing, the District Court acted beyond its authority.

The ideals of federalism explained above weigh in favor of respect for a state's experimentation and respect for a state's sovereignty. The precedents that govern our examination and that of the District Court of a facial challenge to state legislation are consistent with these ideals of federalism, and indeed are consistent with the delicate balance of power explained by Madison in his early writings.

The District Court's preliminary injunction must be vacated.

X. Conclusion and Order

The decision I would make, for the reasons explained in this concurring opinion, would not bar further

proceedings, either in the civil action in which the preliminary injunction was issued or in a civil action newly filed at some future time, if at that time a showing could be made by the complaining party that the Legislative or Executive Branch of the sovereign State of Maine, or an Administrative Agency authorized to act to serve the declared legislative aim of the statute in issue, had taken action that is a threat to legally protected interests of a person or entity (including any out-of-state as well as any in-state person or entity) making the complaint. That person or entity might appropriately seek a form of limited injunctive relief needed to protect identified interests without deeper intrusions on the State of Maine's legitimate interests than would be necessary and appropriate for that purpose.

For the reasons stated in this opinion, the District Court's preliminary injunction should be vacated, and I concur in the judgment of the Court of Appeals, delivered by Judge Bownes, so ordering.

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 00-2446

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff, Appellee,
v.
KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, and MAINE ATTORNEY GENERAL
Defendants, Appellants.

Before
Bownes, *Senior Circuit Judge,*
Keeton and Saris*, *District Judges*

ORDER
Entered: June 13, 2001

Order on Petition by Plaintiff-Appellee For Rehearing En Banc, which subsumes a Petition for a Panel Rehearing.

The panel that heard this case has voted to deny the petition for panel rehearing.

For the following reasons, there can be no action taken on the petition for rehearing en banc. None of the members

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* Of the District of Massachusetts, sitting by designation.

of the panel are eligible to vote on the petition for rehearing en banc. Federal Rule of Appellate Procedure 35(a) provides in pertinent part:

> When Hearing or Rehearing En Banc May Be Ordered. A majority of the circuit judges who are in regular active service may order that an appeal or other proceeding be heard or reheard by the court of appeals en banc.

See United States v. Leichter, 167 F.3d 667 (lst Cir. 1999) (absolute majority of active judges is needed to grant rehearing en banc).

Judges Keeton and Saris are United States District Court Judges and Judge Bownes is a Senior Circuit Court Judge. All of the active Circuit Court Judges with the exception of Chief Judge Torruella have recused themselves from this case. The petition for rehearing en banc must, therefore, be denied.

Chief Judge Torruella wants to be recorded as voting "in favor of rehearing en banc, based on the opinion of the District Court."

Judgment shall issue in accord with the Rules.

By the Court:
Phoebe Morse, Clerk.
By: [JANICE M. O'NEIL]
Chief Deputy Clerk

cc: Bruce C. Gerrity, Esq.
Ann R. Robinson, Esq.
Allen S. Rugg, Esq.
Daniel M. Price, Esq.
Marinn F. Carlson
Kathleen M. Sullivan
Paul Stern, Esq.

Andrew S. Hagler, Esq.
John R. Brautigam, Esq.
Thomas Charles Bradley, Esq.
Arn H. Pearson, Esq.
Steven J. Rosenbaum, Esq.
David H. Remes, Esq.
Daniel J. Popeo, Esq.
Richard A. Samp, Esq.
Edwin D. Schindler

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA
Plaintiff,

v. Civil No. 00-157-B-H

COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, ET AL.,
Defendants.

ORDER ON MOTION FOR PRELIMINARY INJUNCTION[1]

When prescription drugs are covered by insurance or Medicaid, volume buying produces substantially lower prices. But when a private citizen purchases on his or her own, the price is much higher.[2] The Maine Legislature has

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[1] The Motion by Maine Council of Senior Citizens and Viola Quirion for Leave to File a Brief of Amicus Curiae in Opposition to Plaintiff's Motion for a Preliminary Injunction is Granted by agreement.

[2] A minority staff report for the U.S. House Committee on Government Reform and Oversight says that the average retail price is 86 percent higher for the elderly than the price charged to the federal government and most favored customers like HMOs. Minority Staff Report, *Prescription Drug Pricing in the 1st Congressional District of Maine: Drug Companies Profit at the Expense of Older Americans*, Committee on Government Reform

become concerned over these high prescription prices for Maine citizens. It decided that by using Maine's leverage as a large scale purchaser of drugs in the Medicaid market, it could help these people by requiring manufacturers to provide lower prices for them as well. To that end, the Legislature passed L.D. 2599 and the Governor signed it on May 11, 2000.

The Maine legislation does three things that are challenged in this case: (1) it prohibits profiteering and excessive pricing by drug manufacturers, and creates extensive civil penalties to enforce the prohibition; (2) it prohibits manufacturers from altering their distribution schemes so as to escape the Maine law; and (3) it orders the Commissioner of Human Services to negotiate with the drug manufacturers (all of whom are out-of-state) to provide a rebate every time an uninsured Maine citizen buys a prescription at a pharmacy in Maine. Any manufacturers' rebates go into a new state fund, the Rx Fund. Qualifying Maine citizens purchase their prescription medications from Maine pharmacies at a mandated discount; and the manufacturers' rebates in the Rx Fund reimburse the pharmacies for what they have lost. The incentive to make the manufacturers cooperate is the following: the names of those manufacturers who do not participate are to be made public; and their drugs are to be put on a special listing in Maine's Medicaid program, such that prior authorization will be required before those drugs will be approved for any Medicaid reimbursement.[3]

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and Oversight, U.S. House of Representatives, prepared for Rep. Thomas H. Allen, Oct. 9, 1998, at 8.

[3] The Commissioner has proposed a regulation by which the Maine Medicaid Drug Utilization Committee would review any drug slated to go on such a listing. The Committee could then exempt, for medical reasons, specified drugs from the prior

The plaintiff, an association representing drug manufacturers that account for over 75% of brand name drug sales in the United States, has challenged the Maine legislation on the grounds that it violates the interstate Commerce Clause and is preempted by the federal Medicaid statute.[4] On October 19, 2000, I heard a motion for preliminary injunction.

My conclusion: The Maine Legislature has sound reasons for wanting to assist its uninsured citizens who must cope with astronomical prescription drug prices. But in our country, under our Constitution, states cannot legislate outside their boundaries. Whatever power Maine may have over in-state pharmacies, it cannot legislate the amounts that out-of-state manufacturers obtain when they sell to pharmaceutical wholesalers or distributors out-of-state. That is what Maine has tried to do here, in a roundabout way, but the interstate Commerce Clause will not permit it. As for the small proportion of transactions where the manufacturers sell directly into Maine, the rebate program conflicts with the federal Medicaid program and is therefore preempted. As a result, I find that the plaintiff is entitled to a preliminary injunction preventing the enforcement of essential parts of the Maine legislation.

Analysis

1. *Maine's Prohibition on Unconscionable Prices and Unreasonable Profits.* The statute makes it "illegal profiteering" for a manufacturer to "exact[] or demand[] an unconscionable price" or to "exact[] or demand[] prices or terms that lead to any unjust or unreasonable profit." An Act to Establish Fairer Pricing for Prescription Drugs,

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authorization requirement. *See* Proposed Rule: Rules of the Dep't of Human Servs. § 15, Maine Rx Program (2000).

[4] The defendants have not challenged the plaintiff's standing to bring this constitutional challenge.

§ 2697(2), 2000 Me. Legis. Serv. 786 (S.P. 1026) (L.D. 2599) (West) (to be codified at 22 M.R.S.A. § 2697(2)). It is undisputed on the record before me that all the drug manufacturers represented by the plaintiff are located outside the State of Maine, Bantham Decl. ¶ 6, and that by far the greater bulk of their customers—wholesalers and distributors—are likewise outside Maine. There are limited exceptions. Hannaford Bros. Co., located in Maine, buys directly from Roxane Laboratories, Inc. and Boehringer Ingelheim Pharmaceuticals, Inc.; Bindley Western Drug Company, a distributor, has a subsidiary, J.E. Goold, that is located in Maine; and Progressive Distributors, Inc., another distributor, has a facility in Maine. Bilyk Decl. ¶ 5; Feldman Decl. ¶ 8. Under the contracts with these companies, however, the sale from the manufacturer always occurs at the place of business outside Maine—with the exception of Hannaford Bros. Co.[5] In other words, Bindley Western and Progressive Distributors go to other states to buy their products, then import them to Maine.

Where the manufacturers' sales occur outside of Maine, Maine has no authority to regulate the revenues obtained by the manufacturers. Maine's statutory prohibition on profiteering or excess pricing in such transactions is simply unenforceable. I set forth the caselaw concerning extraterritorial legislation in section (3) below.

2. *The Prohibition on Retaliation.* The statute makes it "illegal profiteering" for a manufacturer to "[i]ntentionally prevent[], lessen[] or restrict[] the sale or distribution of prescription drugs in this State in retaliation for the

[5] It appears that title passes in Maine in the case of Roxane and Boehringer sales to Hannaford Bros., Feldman Decl.¶ 7, and Pfizer, Inc. sales pursuant to the Federal Supply Schedule. McPhillips Decl.¶ 7. The record does not disclose whether any Pfizer sales under the Federal Supply Schedule would be subject to the Maine Rx rebate program.

provisions" of the law. Act, § 2697(2)(D), 2000 Me. Legis. Serv. 786 (West) (to be codified at 22 M.R.S.A. § 2697(2)(D)). Obviously, manufacturers might enter Maine and undertake activities that would fall under this provision. The plaintiff wants me to declare, however, that if the manufacturers merely alter their distribution channels out-of-state, they cannot be held liable under this provision. Although that seems to be a reasonable conclusion, it is unnecessary and inappropriate for me to rule at this time. *See Ernst & Young v. Depositors Econ. Protection Corp.*, 45 F.3d 530, 538 (1st Cir 1995) (noting that courts should avoid answering hypothetical questions); *National Conference of Catholic Bishops v. Smith*, 635 F.3d 535, 540 (1st Cir. 1981) (observing that court will not speculate and will not decide dispute without sufficient facts). I have no specific actions by manufacturers on which to base such a ruling, and a Maine court might construe this portion of the statute in a narrow way that would avoid any constitutional issue.

3. *The Rebate Program.*

(a) *The Commerce Clause.*

Under the United States Constitution, Article I, section 8, Congress has the power "[t]o regulate commerce with foreign nations, and among several states, and with the Indian tribes." U.S. Const. art. I, § 8, cl. 3. The question is whether Maine has intruded on this Congressional power.

(i) Market Participation. The State argues that I need not reach the constitutional issue concerning its rebate program. It says that it is not really legislating or regulating, but simply exercising its market power as a volume purchaser of prescription medicines in the Medicaid program.[6] The Supreme Court has held that when a state

[6] Under 42 U.S.C. § 1396r-8(a)(1), manufacturers must enter into a rebate agreement with the federal government or individual states in order for their drugs to be covered under the Medicaid

participates in the market as a buyer or seller rather than as a regulator, it is not subject to the restrictions of the interstate Commerce Clause. Instead, as it said in a case that originated in Maine, Supreme Court cases "stand for the proposition that ... 'under the dormant Commerce Clause, a State acting in its proprietary capacity as a purchaser or seller may "favor its own citizens over others."'" *Camps Newfound/Owatonna, Inc. v. Town of Harrison, Maine*, 520 U.S. 564, 592-93 (1997); *accord National Foreign Trade Council v. Natsios*, 181 F.3d 38, 64 (1st Cir. 1999).[7]

But the "citizen favoring" the Supreme Court has allowed states to indulge in, when they are market participants, has always been in the actual transaction—Boston limiting its construction projects to firms that employ 50% Boston residents on those projects, *White v. Massachusetts*, 460 U.S. 204, 206, 215 (1983); South

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program. *See* 42 U.S.C.A. § 1396(b) (West 1992). According to the agreement, a manufacturer provides a rebate to the states each quarter based on information submitted by the states for the amount of drugs paid for under Medicaid. 42 U.S.C.A. § 1396r-8(1)(A). The amount of the rebate is calculated by a formula in the statute, which incorporates the manufacturer's submission of its average manufacturer price and best price for the covered drugs. 42 U.S.C.A. § 1396r-8(c). In addition, the drug rebate program allows states to require that certain drugs be approved before physicians may dispense them, *see* n.12 *infra*, and requires states to conduct drug review prospectively and retrospectively. 42 U.S.C.A. § 1396r-8(d), (g).

[7] This unfortunate terminology—"dormant Commerce Clause"—refers to Supreme Court cases holding that even where Congress has not used its interstate commerce power to legislate on a particular subject (hence, "dormant" or "negative"), states are not free to intrude in ways that burden commerce. Justice Scalia has noted his disagreement with the principle, *General Motors Corp v. Tracy*, 519 U.S. 278, 312-14 (1997), but it remains good law.

Dakota selling its cement only to South Dakota residents, *Reeves, Inc. v. Stakes*, 447 U.S. 429, 440 (1980); Maryland purchasing junked cars from its residents with less paper documentation than from out-of-staters, *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 809-10 (1976). None of the cases supports extending this market power to other activities. Here, Maine is not favoring its citizens in the actual transaction when it buys prescription drugs in the Medicaid program. (An example of permitted favoritism would be buying only from Maine manufacturers, if there were any.) Instead, it is trying to use its leverage there to achieve a social, regulatory goal elsewhere—to reduce the price of prescription medications for Maine citizens who do not participate in Medicaid and who do not have private insurance.[8] That is a worthy legislative goal, but it is not the kind of market participation that the Supreme Court has freed from interstate commerce power limits. In fact, the Supreme Court struck down Alaska's attempt to sell its timber only to customers who would also agree to process the purchased timber in Alaska, *South-Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 96-98 (1984), finding the program to be tantamount to regulation.[9] The Supreme Court reasoned that Alaska was impermissibly trying to use its leverage in the timber market, where it was a participant, in order "to exert a regulatory effect in the processing

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[8] According to the statute, "the State shall serve as a pharmacy benefit manager...." Act, § 2681, 2000 Me. Legis. Serv. 786 (West) (to be codified at 22 M.R.S.A. § 2681). The State does not, however, buy the drugs. If it did, the analysis and result might be different.

[9] The Court also struck down Wisconsin's refusal to make any state purchases from repeat labor law violators, *Wisconsin Dep't of Industry, Labor & Human Relations v. Gould, Inc.*, 475 U.S. 282, 289 (1986), on the same ground, that it was in fact a regulatory measure.

market, in which it is not a participant." 467 U.S. at 98. Likewise here, Maine is using its leverage in the Medicaid market, where it is a participant, to exert a regulatory effect in the uninsured market for prescription drugs, in which it is not a participant. As the First Circuit has observed (quoting approvingly from the *Wunnicke* plurality decision): "the market participant 'doctrine is not carte blanche to impose any conditions that the State has the economic power to dictate, and does not validate any requirement merely because the State imposes it upon someone with whom it is on contractual privity.'" *National Foreign Trade Council*, 181 F.3d at 63. As a result, Maine's Rx program cannot escape interstate Commerce Clause limitations.

(ii) Constitutionality. Treating the rebate program as an exercise of Maine's regulatory or police power, then, I must decide whether it is constitutional. First, the State is correct that this is not the typical attempt to favor in-state businesses over out-of-state businesses. There are no Maine drug manufacturers, and no suggestion on this record that Maine is in the process of trying to establish a favorable environment to bring them here. Instead, the rebate program applies to any manufacturer, whether or not it is from Maine. Maine is trying to benefit its residents, specifically those who are uninsured, in the purchase of prescription medicines; but it is not trying to better their lot over out-of-staters.[10] So the question is not whether Maine is discriminating against out-of-staters, but simply whether it has the power to extend its authority to out-of-state manufacturers. I conclude that the answer for most transactions is "no," on bedrock principles concerning the

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[10] Of course, if the drug manufacturers are unwilling just to give up their profits, any lowering of prices to uninsured Maine consumers will have to result in an increase somewhere else—prices to out-of-state buyers, or in Maine's Medicaid program, or in insured purchases.

territorial limits of a state's power established by the Supreme Court at least as far back as 1935.

In *Baldwin v. G.A.F. Seelig*, Justice Cardozo wrote:

> New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there. So much is not disputed. New York is equally without power to prohibit the introduction within her territory of milk of wholesome quality acquired in Vermont, whether at high prices or at low ones. This again is not disputed.

294 U.S. 511, 521 (1935). If we change the names of the states, and substitute prescription medications for milk, the statements are equally applicable here to distributors that acquire prescription drugs outside the state of Maine before they bring them here. Maine may have power over what pharmacists later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the prices paid earlier in transactions in other states. The Supreme Court reiterated these principles as recently as 1989:

> Taken together, our cases concerning the extraterritorial effects of state economic regulation stand at a minimum for the following propositions: First, the "Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State," . . . . Second, a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature. The critical inquiry is whether the

> practical effect of the regulation is to control conduct beyond the boundaries of the State.

Healy v. Beer Institute, 491 U.S. 324, 336 (1989) (internal citations omitted). It is undisputable that the practical effect of what Maine has done here is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine. Under the Maine rebate program, whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced when the drug comes to Maine. Because Maine has no power thus to extend its power extraterritorially and to impose this burden on interstate commerce, it is irrelevant whether its program actually discriminates against out-of-staters. *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 579 (1986) (stating that state statutes are struck down if they favor in-state economic interests over out-of-state, *or* if they discriminate against interstate commerce *or* if they simply regulate interstate commerce directly, whether or not they discriminate). *Accord Edgar v. MITE Corp.*, 457 U.S. 624, 644 ("Insofar as the Illinois law burdens out-of-state transactions, there is nothing to be weighed in the balance to sustain the law."); Laurence H. Tribe, *American Constitutional Law* § 6-8 (3d ed. 2000).

(b) *Supremacy Clause*. The plaintiff manufacturers concede that the Commerce Clause limitations on Maine's power to legislate outside its borders do not prevent Maine from regulating sales to Maine-based distributors (*e.g.*, Hannaford Bros., J.E. Goold, Progressive Distributors). Instead, I must decide whether the federal Medicaid program invalidates Maine law as to such transactions by virtue of the Supremacy Clause.

Under Article VI of the United States Constitution:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof;

> and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land, and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. art. VI. There is no question that Congress has legislated an extensive and detailed federal Medicaid program. But nowhere has it expressly forbidden what Maine has done.[11] The Supremacy Clause issue, therefore, is whether there is "implied" preemption on the basis that Maine's legislation is inconsistent with Medicaid's objectives. This inquiry boils down to a question of Congressional intent. *See Pacific Gas v. State Energy Resources Conserv. & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983); *Massachusetts Ass'n of HMOs v. Ruthhardt*, 194 F.3d 176, 178 (1st Cir. 1999); *O'Brien v. Massachusetts Bay Trans. Auth.*, 162 F.3d 40, 43 (1st Cir. 1998).

"Preemption may, of course, be inferred from the goals of a federal statute." *French v. Pan Am Express, Inc.*, 869 F.2d 1, 5 (1st Cir. 1989). The purposes of the federal Medicaid program are straightforward: to provide medical services, including prescription drugs, 42 C.F.R. §§ 456.702-3 (West 2000), to those with medical needs who qualify under Medicaid's eligibility standards. 42 U.S.C.A. § 1396 (West 1992); *Mayburg v. Secretary of Health & Human Servs.*, 740 F.2d 100, 103 (1st Cir. 1984) (noting the general principle that the Social Security Act should be broadly construed "to carry out Congress's intent to provide

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[11] Congress recognizes the existence of prior authorization programs for prescription drugs and specifies two requirements: (1) a 24-hour response to any request for authorization; (2) a 72-hour emergency supply where authorization is unavailable. 42 U.S.C.A. § 1396r-8(d)(5) (West 1992). Maine satisfies both requirements. *See* Code Me. R. §§ 80.07-3-80.07-4 (1979).

medical expense coverage for all qualifying individuals"). To that end, Congress has demanded that any state restriction on drug distribution "provide such safeguards as may be necessary to assure that care and services ... will be provided, *in a manner consistent with the best interest of Medicaid's requirements*." 42 U.S.C.A. § 1396c(a)(19) (West 1992) (emphasis added). Nowhere has Congress suggested that the federal Medicaid program can be used to further the interests of *non*-Medicaid recipients. Maine asserts that under its proposed regulations Maine will comply with federal requirements; that the "Department of Human Services will not deny a single Medicaid recipient access to the safest and most efficacious prescription drug therapy indicated for their individual medical circumstances." Def. Mem. in Opp'n to Mot. for Prelim. Inj. at 29. But Maine can point to no *Medicaid* purpose in this new prior authorization requirement that Maine has added for Medicaid prescription drugs. Maine has not just passed a law that might conflict with the objectives of a federal law. It has actually taken the federal Medicaid program and altered it to serve Maine's local purposes. If Maine can use its authority over Medicaid authorization to leverage drug manufacturer rebates for the benefit of uninsured citizens, then it can just as easily put the rebates into a state program for highway and bridge construction or school funding. All these purposes are outside the scope of the federal Medicaid program. No matter how modest an obstacle the new prior authorization amounts to (the parties disagree on the severity of the obstacle), it is an obstacle—drugs on the list must be approved by the state Medicaid Medical Director before they can be dispensed or prescribed—and therefore "an obstacle to the accomplishment and execution of the Congressional objectives of federal Medicaid." *See Pacific Gas*, 461 U.S.

at 402-03; *Ruthhardt*, 194 F.3d at 178; *Beckley Capital Ltd. P'ship v. DiGeronimo*, 184 F.3d 52, 56 (1st Cir. 1999); *O'Brien*, 162 F.3d at 43.[12] The Supremacy Clause prevents

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[12] It may never have occurred to Congress that the Medicaid program could be hijacked to provide leverage for other purposes. Instead, the legislative history reveals that Congress contemplated prior authorization only in narrow circumstances: "As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care." H. Rep. No. 101-881 at 98 (Oct. 16, 1990) *reprinted in* 1990 U.S.C.C.A.N. 2016-1, 2110. Maine's Rx rebate program has nothing to do with these concerns of unnecessary use of prescription drugs or with safeguarding Medicaid payments.

The Secretary (here, HCFA) has not promulgated a final regulation on prior authorization, *see* 65 Fed. Reg. 22802, 22805 (Apr. 24, 2000), and therefore I do not apply *Chevron* analysis under *Visiting Nurses Ass'n of North Shore, Inc. v. Bullen*, 93 F.3d 997, 1006-09 (1st Cir. 1996). *See Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1375 n.15 (11th Cir. 1999) (refusing to give the FDA's proposed rule any authoritative weight or deference); *Public Citizen, Inc. v. Shalala*, 923 F. Supp. 13, 18 n.6 (D.D.C. 1996) (noting that "tentative conclusion articulated in a nonfinal proposed rules does not command deference from the Court nor is it binding on the agency"). *But see Vanscoter v. Sullivan*, 920 F.2d 1441, 1445 (9th Cir. 1990) (deferring to agency interpretation expressed in a proposed rule). A comment (comments are not entitled to deference, *Visiting Nurses Ass'n*, 93 F.3d at 1007) concerning the proposed regulation does support the proposition that prior authorization can be used for clinical or economic purposes and refers approvingly to a state seeking a larger rebate. Medicaid Program: Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, 60 Fed. Reg. 48442, 48473 (Sept. 19, 1995). But there is *no* suggestion that HCFA was discussing anything other than a larger rebate that would benefit the *Medicaid* program.

Maine from diverting the Medicaid program to this other objective, however worthy an objective it may be.

(c) *Voluntariness*. The State has not argued directly that its rebate/Rx program is voluntary and therefore not to be considered a forbidden exercise of state power. But there is the flavor of such an argument—that this is all just a matter of negotiation with the Commissioner—and I therefore address it. Is negotiation and participation in the rebate program simply a voluntary decision that out-of-state manufacturers make for the greater good? If public listing of those refusing to negotiate with the Commissioner were the only incentive, I would find no serious constitutional issue. Nothing prevents a state from seeking voluntary largess from companies, even out-of-state companies, and then publicly recognizing them for their civic-mindedness or publicly stigmatizing those who do not participate for their lack of civic-mindedness. There is likewise no prohibition on the Commissioner merely negotiating with companies to try to persuade them to take action that will lower the prices to Maine citizens. Instead, the bite here—if there is any—is the new condition that drugs of an uncooperative manufacturer require prior approval before they can qualify for Medicaid reimbursement. Indeed, the statute says that manufacturers "shall enter" into rebate agreements and speaks of negotiating the "rebate *required* from a manufacturer." Act, § 2681(3), (4), 2000 Me. Legis. Serv. 786 (2000) (to be codified at 22 M.R.S.A. § 2681(3), (4)) (emphasis added).[13] It is only common sense to conclude

[13] The L.D. that was ultimately enacted came from Senate Amendment A of May 11, 2000, to S.P. 1026, L.D. 2599. According to the Senate Amendment "A" Summary, the amendment "directs the department to require prior authorization for the dispensing of drugs in the Medicaid program that are provided from manufacturers and labelers who do not enter into

that the requirement has been put in the legislation because the Legislature thought it would create *some* bite to give the Commissioner negotiating leverage for the Rx rebate program. The State makes no argument that the new condition of prior approval serves any purpose of the Medicaid program.[14] And the State has not contested the plaintiff's affidavits that a prior authorization listing often results in substantially reduced market share for a manufacturer. *See, e.g.*, Moules Aff. ¶¶ 7, 9-4; Bilyk Decl. ¶ 6. It is, therefore, not a voluntary program.

But only the prior approval requirement creates the coercion that makes the rebate/Rx program unconstitutional. If the State wants to continue the program as a voluntary program with public stigma being the only incentive, it may do so.

rebate agreements with the State under the Maine Rx Program." ¶ 6.

[14] Instead, the Medical Director for the Maine Bureau of Medicaid Services, which administers Maine's Medicaid Program, states that the "primary purpose of a prior authorization requirement is to ensure that a drug is not being used inappropriately" and is not designed "to limit the use of that drug." Clifford Aff. ¶¶ 6, 7. Indeed, the Commissioner has recently proposed a regulation to make clear that medically necessary drugs will still be approved and in some instances may even escape the prior authorization requirement despite a manufacturer's failure to negotiate a rebate. *See* Proposed Rule: Rules of the Dep't of Human Servs., § 15, Maine Rx Program (2000) (to be codified at Code Me. R. § 15). The reason for this narrowing of the program is apparently to forestall Medicaid challenges and, according to the Assistant Attorney General at oral argument, to recognize that the Department is directed to "impose prior authorization requirements in the Medicaid program under this title, *as permitted by law*...." Act, § 2681(7), 2000 Me. Legis. Serv. 786 (West) (to be codified at 22 M.R.S.A. § 2681(7)) (emphasis added).

CONCLUSION

For purposes of the preliminary injunction motion, the record is essentially undisputed. On that record, I find the plaintiff's likelihood of success on the merits of most of its constitutional challenges to be overwhelming. That being so, the State's interest in forestalling the preliminary injunction is weak. The State has a strong interest in assisting its economically and medically needy citizens, but not through unconstitutional legislation. The public interest is the same. The plaintiff's interest is strong because, under the Eleventh Amendment manufacturers would be unable to recover payments they made to the State, and by entering the rebate agreements, may be submitting themselves contractually to an obligation, regardless. Accordingly, the plaintiff is entitled to a preliminary injunction, *see Philip Morris, Inc. v. Harshbarger*, 159 F.3d 670, 673-74 (1st Cir. 1998); *Ross-Simons of Warwick, Inc. v. Baccaral, Inc.*, 102 F.3d 12, 15 (1st Cir. 1991). No security is appropriate under Fed. R. Civ. P. 65(c), and the State has not requested security.

The Commissioner is hereby PRELIMINARILY ENJOINED from penalizing manufacturers, by placing their drugs on prior listing status, for refusing to negotiate or to pay a rebate to Maine's Rx program.

The Attorney General is hereby PRELIMINARILY ENJOINED from seeking to enforce the illegal profiteering portion of the statute against transactions that occur outside the State of Maine, even if the prescription drugs eventually end up and are ultimately purchased in Maine.

SO ORDERED.

DATED THIS [26th] DAY OF OCTOBER 2000.

[signed]
D. BROCK HORNBY
UNITED STATES DISTRICT JUDGE

SOCIAL SECURITY ACT § 1927
42 U.S.C. § 1396r-8 (in pertinent part)

§ 1396r-8. Payment for covered outpatient drugs.

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) of this section with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), * * *

* * * *

(b) Terms of rebate agreement

(1) Periodic rebates

(A) In general

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) of this section for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) of this section or an agreement described in subsection (a)(4) of this section) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title.

(2) State provision of information

(A) State responsibility

Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

(B) Audits

A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price information

(A) In general

Each manufacturer with an agreement in effect under this section shall report to the Secretary--

(i) not later than 30 days after the last day of each rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1)

of this section) and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B) of this section) for covered outpatient drugs for the rebate period under the agreement, and

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1) of this section) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs.

* * * *

(c) Determination of amount of rebate

(1) Basic rebate for single source drugs and innovator multiple source drugs

(A) In general

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8) of this section) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of--

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of--

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified

in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) Range of rebates required

(i) Minimum rebate percentage

For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning--

* * * *

(V) after December 31, 1995, is 15.1 percent.

* * * *

(C) Best price defined

For purposes of this section--

(i) In general

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding--

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of Title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section;

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State

pharmaceutical assistance program; and

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.

(ii) Special rules

The term "best price"--

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and

(III) shall not take into account prices that are merely nominal in amount.

(2) Additional rebate for single source and innovator multiple source drugs

(A) In general

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of--

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which--

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar

quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

* * * *

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) of this section or in effect pursuant to subsection (a)(4) of this section; or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(3) Update of drug listings

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee

consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3) of this section).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6) of this section), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval--

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

* * * *

(k) Definitions

In this section--

(1) Average manufacturer price

The term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

* * * *

(5) Manufacturer

The term "manufacturer" means any entity which is engaged in--

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

* * * *

(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug

(A) Defined

(i) Multiple source drug

The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which--

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug

Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the State during the period.

(ii) Innovator multiple source drug

The term "innovator multiple source drug" means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) Noninnovator multiple source drug

The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) Single source drug

The term "single source drug" means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) Exception

Subparagraph (A)(1)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(1)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) Definitions

For purposes of this paragraph--

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

* * * *

(9) State agency

The term "State agency" means the agency designated under section 1396a(a)(5) of this title to administer or supervise the administration of the State plan for medical assistance.

STATE OF MAINE

IN THE YEAR OF OUR LORD
TWO THOUSAND

S. P. 1026 -L. D. 2599
An Act to Establish Fairer Pricing for Prescription Drugs

Be it enacted by the People of the State of Maine as follows:

PART A

Sec. A-l. 5 MRSA §12004-I, sub-§47-E is enacted to read:

47-E Human Services	Prescription Drug Advisory Commission	Expenses Legislative Per Diem For Nonsalaried Or Nonpaid Public Members	22 MRSA §2692, sub-§6

Sec. A-2. 22 MRSA §254-B, as enacted by PL 1999, c. 431, §1, is repealed.

Sec. A-3. 22 MRSA c. 603 is enacted to read:

CHAPTER 603
PRESCRIPTION DRUG ACCESS
SUBCHAPTER I

MAINE RX PROGRAM

§2681. Maine Rx Program established

The Maine Rx Program, referred to in this Subchapter as the "program," is established to reduce prescription drug prices for residents of the State. The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a pharmacy benefit manager in establishing rebates and discounts on behalf of qualified residents.

1. Program Goals. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare. It is not the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter.

2. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Average wholesale price" means the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.

B. "Initial discounted price" means a price that is less than or equal to the average wholesale price, minus 6%, plus the dispensing fee provided under the Medicaid

program under this Title.

C. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

D. "Participating retail pharmacy" or "retail pharmacy" means a retail pharmacy located in this State, or another business licensed to dispense prescription drugs in this State, that participates in the program and that provides discounted prices to residents as provided in subsection 5.

E. "Pharmacy benefit manager" means an entity that procures prescription drugs at a negotiated rate under a contract.

F. "Qualified resident" means a resident of the State who has obtained from the department a Maine Rx enrollment card.

G. "Secondary discounted price" means a price that is equal to or less than the initial discounted price minus the amount of any rebate paid by the State to the participating retail pharmacy.

3. Rebate agreement. A drug manufacturer or labeler that sells prescription drugs in this State through the elderly low-cost drug program under section 254 or any other publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program. The rebate agreement must require the manufacturer or labeler to make rebate payments to the State each calendar quarter or according to a schedule established by the department.

4. Rebate amount. The commissioner shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

A. The commissioner shall take into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs and any other information on prescription drug prices and price discounts.

B. The commissioner shall use the commissioner's best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.

C. With respect to the rebate taking effect no later than October 1, 2001, the commissioner shall use the commissioner's best efforts to obtain an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government.

5. Discounted prices for qualified residents. Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement pursuant to subsection 3 shall discount the retail price of those drugs sold to qualified residents.

A. The department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead and incentive payments.

B. Beginning January 1, 2001, a participating retail pharmacy shall offer the initial discounted price.

C. No later than October 1, 2001, a participating retail pharmacy shall offer the secondary discounted price.

D. In determining the amount of discounted prices, the department shall consider an average of all rebates

provided pursuant to subsection 4, weighted by sales of drugs subject to these rebates over the most recent 12-month period for which the information is available.

6. Operation of program. The requirements of this subsection apply to participating retail pharmacies.

A. The Maine Board of Pharmacy shall adopt rules requiring disclosure by participating retail pharmacies to qualified residents of the amount of savings provided as a result of the program. The rules must consider and protect information that is proprietary in nature. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

B. The department may not impose transaction charges under this program on retail pharmacies that submit claims or receive payments under the program.

C. A participating retail pharmacy shall submit claims to the department to verify the amount charged to qualified residents under subsection 5.

D. On a weekly or biweekly basis, the department must reimburse a participating retail pharmacy for discounted prices provided to qualified residents under subsection 5 and professional fees, which must be set by the commissioner. The amount of the initial professional fee must be set at $3 per prescription.

E. The department shall collect utilization date from the participating retail pharmacies submitting claims necessary to calculate the amount of the rebate from the manufacturer or labeler. The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule or regulations.

7. Action with regard to nonparticipating manufacturers and labelers. The names of manufacturers and labelers who do not enter into rebate agreements

pursuant to this subchapter are public information. The department shall release this information to health care providers and the public. The department shall impose prior authorization requirements in the Medicaid program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers.

8. Discrepancies in rebate amounts. Discrepancies in rebate amounts must be resolved using the process established in this subsection.

A. If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the department for any additional amount due.

B. If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer any excess payment made by the manufacturer or labeler.

C. Following the procedures established in paragraph A or B, either the department or the manufacturer or labeler may request a hearing before the Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

9. Dedicated fund. The Maine Rx Dedicated Fund, referred to in this section as the "fund," is established to receive revenue from manufacturers and labelers who pay rebates as provided in subsection 4 and any appropriations or allocations designated for the fund. The purposes of the fund are to: reimburse retail pharmacies for discounted prices provided to qualified residents pursuant to subsection 5; to reimburse the department for contracted services, administrative and associated computer costs, professional fees paid to participating retail pharmacies and other reasonable program costs; and to benefit the elderly low-cost drug program under section 254. The fund also must be used in fiscal year 2002-03 to repay the working capital advance made to the program during fiscal year 2000-01 from the Trust Fund for a Healthy Maine, established in section 1512. The fund is a nonlapsing dedicated fund. Interest on fund balances accrues to the fund. Surplus funds in the fund must be used for the benefit of the program. Notwithstanding Title 5, section 1585, surplus funds may also be transferred to the elderly low-cost drug program established under section 254.

10. Annual summary report. The department shall report the enrollment and financial status of the program to the Legislature by the 2nd week in January each year.

11. Obligations of department. The department shall establish simplified procedures for determining eligibility and issuing Maine Rx enrollment cards to qualified residents and shall undertake outreach efforts to build public awareness of the program and maximize enrollment of qualified residents. The department may adjust the requirements and terms of the program to accommodate any new federally funded prescription drug programs.

12. Contracting. The department may contract with a 3rd-party or 3rd-parties to administer any or all components of the program, including, but not limited to, outreach, eligibility, claims, administration and rebate recovery and

redistribution.

13. Medical assistance programs. The department shall administer the program and other medical and pharmaceutical assistance programs under this Title in a manner that is advantageous to the programs and to the enrollees in those programs. In implementing this subsection the department may coordinate the other programs and this program and may take actions to enhance efficiency, reduce the cost of prescription drugs and maximize the benefits to the programs and enrollees, including providing the benefits of this program to enrollees in other programs.

14. Rulemaking. The department may adopt rules to implement the provisions of this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

15. Waivers. The department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this subchapter.

SUBCHAPTER II
PRESCRIPTION DRUG PRICE REDUCTION ACT

§2691. Short Title; purpose

This subchapter may be known and cited as the "Prescription Drug Price Reduction Act." The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature as a positive measure to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare of Maine residents.

§2692. Prescription Drug Advisory Commission

The Prescription Drug Advisory Commission, referred to in this subchapter as the "commission," is established to review access to and the pricing of prescription drugs for residents of the State, to advise the commissioner on prescription drug pricing and to provide periodic reports to the commissioner, the Governor and the Legislature.

1. Membership. The commission consists of the following 12 members:

A. Three members of the public, appointed by the President of the Senate, one of whom must represent the interests of senior citizens. Of the initial appointees, one must be appointed for a 2-year term and 2 for 3-year terms;

B. Three members of the public, appointed by the Speaker of the House, one of whom must represent the interests of senior citizens. Of the initial appointees, one must be appointed for a 2-year term and 2 for 3-year terms;

C. Two members of the health care community who are authorized by the laws of this State to prescribe drugs, appointed by the Governor. Of the initial appointees, one must be appointed for a 2-year term and one for a 3-year term;

D. Two pharmacists, appointed by the Governor. Of the initial appointees, one must be appointed for a 2-year term and one for a 3-year term. To be appointed to and remain on the commission, each pharmacist must:

(1) Be licensed to practice pharmacy and be engaged in the practice of retail pharmacy in this State;

(2) Have at least 5 years of experience in this State as a licensed pharmacist; and

(3) Be a resident of this State; and

E. The Director of the Bureau of Medical Services and the Commissioner of Professional and Financial Regulation, or their designees, who shall serve as ex officio, nonvoting members.

2. Terms. With the exception of the initial appointees, all members of the commission serve for terms of 3 years and may be reappointed. With the exception of the pharmacist members, if the profession or qualifications of a commission member change during the term of commission membership, the member may continue to complete the term for which the appointment was made.

3. Meetings; chair. The commission shall meet at least 4 times per year. The members shall select a chair from among the members. Additional meetings may be called by the chair.

4. Duties. The duties of the commission include the following:

A. To review access to prescription drugs for residents of the State, including, but not limited to, pricing and affordability information;

B. To advise the commissioner on access to prescription drugs and prescription drug prices, including, but not limited to, insurance and 3rd-party payments for prescription drugs, the need for maximum retail prices, and, if maximum retail prices are established, the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs and the procedures for phasing out or terminating maximum retail prices;

C. To advise the commissioner on the adoption of rules necessary to implement this subchapter; and

D. To report to the commissioner, the Legislature and the Governor by April 1, 2001, and annually thereafter by the 2nd week in January, including in the report any recommendations for action regarding access to and the pricing of prescription drugs.

5. Staffing. The department shall provide staffing for the commission.

6. Compensation. Public members not otherwise compensated by their employers or other entities whom they represent are entitled to receive reimbursement of necessary expenses and a per diem equal to the legislative per diem for their attendance at authorized meetings of the commission.

7. Cooperation. In performing its duties, the commission shall work with the department, the Maine Board of Pharmacy and the Department of Professional and Financial Regulation.

§2693. Emergency drug pricing

In order to achieve the public health purposes listed in section 2691, maximum retail prices for prescription drugs sold in Maine may be established pursuant to this section.

1. Emergency drug pricing procedures. The following provisions apply to determinations regarding maximum retail prices for prescription drugs and to the procedures for establishing those prices.

A. By July 1, 2002, the department shall adopt rules establishing the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail process of selected drugs and the procedures for phasing out or terminating maximum retail prices. Prior to adopting rules pursuant to this paragraph, the commissioner shall consult with and consider the

recommendations of the commission regarding the rules.

B. By January 5, 2003, the commissioner shall determine whether the cost of prescription drugs provided to qualified residents under the Maine Rx Program pursuant to subchapter I is reasonably comparable to the lowest cost paid for the same drugs delivered or dispensed in the State. In making this determination the following provisions apply.

(1) The commissioner shall review prescription drug use in the Medicaid program using data from the most recent 6-month period for which data is available.

(2) Using the data reviewed in subparagraph (1), the commissioner shall determine the 100 drugs for which the most units were provided and the 100 drugs for which the total cost was the highest.

(3) For each prescription drug listed in subparagraph (2), the commissioner shall determine the cost for each drug for qualified residents provided those drugs under the Maine Rx Program on a certain date. The average cost for each such drug must be calculated.

(4) For each prescription drug listed in subparagraph (2), the commissioner shall determine the lowest cost for each drug paid by any purchaser on the date that is used for subparagraph (3) delivered or dispensed in the State, taking into consideration the federal supply schedule and prices paid by pharmaceutical benefits managers and by large purchasers and excluding drugs purchased through the Maine Rx Program. The average cost for each such drug must be calculated.

(5) If the average cost for one or more prescription drugs under the Maine Rx Program as

determined in subparagraph (3) is not reasonably comparable to the average lowest cost for the same drug or drugs as determined in subparagraph (4), the commissioner shall establish maximum retail prices for any or all prescription drugs sold in the State. Maximum prescription drug prices established under this subparagraph must take effect July 1, 2003.

C. In establishing maximum retail prices under this paragraph, the commissioner shall consider the advice of the commission and shall follow procedures set forth by rules adopted by the department.

D. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A.

2. Select prescription drugs. In making a determination under this section the commissioner may rely on pricing information on a selected number of prescription drugs if that list is representative of the prescription drug needs of the residents of the State and is made public as part of the process of establishing maximum retail prices.

3. Public health or welfare. The commissioner may take actions that the commissioner determines necessary if there is a severe limitation or shortage of or lack of access to prescription drugs in the State that could threaten or endanger the public health or welfare.

4. Appeals. A retailer of prescription drugs may appeal the maximum retail price of a prescription drug established pursuant to this section in accordance with the Maine Administrative Procedure Act.

5. Enforcement. A violation of the maximum retail prices established under this section is a violation of the Maine Unfair Trade Practices Act.

§2694. Rulemaking

With the exception of rules designated in this subchapter as major substantive rules, rules adopted pursuant to this subchapter are routine technical rules as defined by Title 5, chapter 375, subchapter II-A.

SUBCHAPTER III

PROFITEERING IN PRESCRIPTION DRUGS

§2697. Profiteering in prescription drugs

Prescription drugs are a necessity of life. Profiteering in prescription drugs is unlawful and is subject to the provisions of this section. The provisions of this section apply to manufacturers, distributors and labelers of prescription drugs.

1. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

B. "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

2. Profiteering. A manufacturer, distributor or labeler of prescription drugs engages in illegal profiteering if that manufacturer, distributor or labeler:

A. Exacts or demands an unconscionable price;

B. Exacts or demands prices or terms that lead to any unjust or unreasonable profit;

C. Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or

D. Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions of this chapter.

3. Right of action and damages. The State may bring a civil action in District Court or Superior Court for a direct or indirect injury to any person, group of persons, the State or political subdivision of the State caused by a violation of this subchapter. There is a right to a jury trial in any action brought in Superior Court under this section. If the State prevails, the defendant shall pay 3 times the amount of damages and the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees. For a willful or repeated violation of this section, punitive damages may be awarded. After deduction of the costs of distribution, the damages must be equitably distributed by the State to all injured parties.

4. Civil violation. Each violation of this section is a civil violation for which the Attorney General may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount not to exceed $100,000, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

5. Unfair trade practice. A violation of this section is also a violation of the Maine Unfair Trade Practices Act.

§2693. Investigation by Attorney General

The Attorney General, upon the Attorney General's own initiative or upon petition of the commissioner or of 50 or more residents of the State, shall investigate suspected violations of this subchapter.

The Attorney General may require, by summons, the attendance and testimony of witnesses and the production of books and papers before the Attorney General related to any such matter under investigation. The summons must be served in the same manner as summonses for witnesses in criminal cases, and all provisions of law related to criminal cases apply to summonses issued under this section so far as they are applicable. All investigations or hearings under this section to which witnesses are summoned or called upon to testify or to produce books, records or correspondence are public or private at the choice of the person summoned and must be held in the county where the act to be investigated is alleged to have been committed, or if the investigation is on petition, it must be held in the county in which the petitioners reside. The expense of the investigation must be paid from the appropriation provided in Title 5, section 203.

A Justice of the Superior Court may by order, upon application of the Attorney General, compel the attendance of witnesses, the production of books and papers, including correspondence, and the giving of testimony before the Attorney General in the same manner and to the same extent as before the Superior Court. Any failure to obey such an order may be punishable by that court as a contempt.

Sec. A-4. Agreements with governments of other jurisdictions and other entities. The State may negotiate and enter into purchasing alliances and regional strategies with the governments of other jurisdictions and with other public and private entities for the purpose of reducing prescription drug prices for residents of the State.

Sec. A-5. Findings; intent; purpose.

1. Findings. The Legislature makes the following findings.

A. Pharmaceutical companies are charging the

citizens of Maine excessive prices for prescription drugs, denying Maine citizens access to medically necessary health care and thereby threatening their health and safety. Many Maine citizens are admitted to or treated at hospitals each year because they can not afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others must enter expensive institutional care settings because they can not afford their necessary prescription drugs that could have supported them outside of an institution. All Maine citizens are threatened by the possibility that when they need medically necessary prescription drugs most they may be unable to afford their doctor's recommended treatment.

B. Citizens of Maine and other Americans pay the highest prices in the world for prescription drugs, prices that result in extremely high profits for pharmaceutical companies.

C. Prescription drug costs represent the fastest growing item in health care and are a driving force in rapidly increasing hospital costs and insurance rates.

D. Excessive pricing for prescription drugs threatens Maine's ability to assist with the health care costs of Maine citizens, undermines the financial capacity of Maine communities to meet the educational needs of Maine children, hurts the ability of the Maine business community to provide health insurance coverage to Maine's work force and has a negative effect on Maine's economy. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents.

2. Intent. It is the intent of the Legislature to provide access for all Maine citizens to medically necessary prescription drugs at the lowest possible prices.

3. Purpose. This law is enacted by the Legislature as a

positive measure to make prescription drugs more affordable for Maine residents, thereby increasing the overall health of our families, benefiting employers and employees and the fiscal strength of our society, promoting healthy communities and increasing the public health and welfare.

Sec. A-6. Appointments; first meeting of Prescription Drug Advisory Commission. All appointments must be completed no later than 30 days following the effective date of this Act. The appointing authorities shall notify the Executive Director of the Legislative Council upon making their appointments. The Chair of the Legislative Council shall call the first meeting of the commission within 30 days after notification that appointments have been completed. At the first meeting of the commission, the members shall select a chair from among the members.

Sec. A-7. Working capital advance. Notwithstanding the Maine Revised Statutes, Title 22, section 1511, subsection 3 and section 1512, the State Controller is authorized to advance to the Maine Rx Dedicated Fund in the Department of Human Services $4,582,500 from the Trust Fund for a Healthy Maine no later than January 1, 2001. These funds may be allotted by financial order upon the recommendation of the State Budget Officer and approval of the Governor. These funds must be returned to the Trust Fund for a Healthy Maine from the Maine Rx Dedicated Fund no later than June 30, 2005.

Sec. A-8. Appropriation. The following funds are appropriated from the General Fund to carry out the purposes of this Part.

HUMAN SERVICES, DEPARTMENT OF 2000-01

Maine Rx Program

Positions – Legislative Count	(6.000)
Personal Services	$148,330
All Other	$502,750

Provides for the one-time appropriation of funds to establish the Maine Rx Program, including the establishment of 6 additional positions and related operating costs, for outreach activities, to contract for claims management and services and for costs associated with the issuance of prescription cards.

DEPARTMENT OF HUMAN SERVICES	
TOTAL	$651,080

ATTORNEY GENERAL, DEPARTMENT OF THE

Administration – Attorney General

Positions – Legislative Count	(1.000)
Personal Services	$46,745
All Other	$5,340
TOTAL	$52,085

Provides one-time funds for one Assistant Attorney General position and related operating costs due to the establishment of

the Maine Rx Program.

Fair Drug Pricing Contingent Account

All Other	$130,000

Provides one-time funds to support litigation costs associated with the Maine Rx Program. Any balance remaining at the end of each fiscal year may not lapse but must be carried forward to be used for the same purpose.

DEPARTMENT OF THE ATTORNEY GENERAL	
TOTAL	$182,085
TOTAL APPROPRIATIONS	$833,165

Sec. A-9. Allocation. The following funds are allocated from the Other Special Revenue funds to carry out the purposes of this Part.

PROFEFSSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF	2000-01

Licensing and Enforcement

All Other	$2,500

Provides for the allocation of funds for the costs associated with the Maine Board of Pharmacy to adopt rules associated with

the Maine Rx Program.

PART B

Sec. B-1. 22 MRSA §254, sub-§8, as corrected by RR 1999, c. 1, §27, is amended to read:

8. Drug rebate program. Effective May 1, 1992, payment must be denied for drugs from manufacturers that do not enter into a rebate agreement with the department for prescription drugs included in the list of approved drugs under this program. Each agreement must provide that the pharmaceutical manufacturer make rebate payments for both the basic and supplemental components of the program to the department according to the following schedule.

~~A. For the period beginning May 1, 1992 and ending September 30, 1992, the rebate percentage is equal to 11% of the manufacturer's wholesale price for the total number of dosage units of each form and strength of a prescription drug that the department reports as reimbursed to providers of prescription drugs, provided payments are not due until 30 days following the manufacturer's receipt of utilization data supplied by the department, including the number of dosage units reimbursed to providers of prescription drugs during the period for which payment is due.~~

B. For the quarters beginning October 1, 1992, the rebate percentage is equal to the percentage recommended by the federal Health Care Financing Administration of the manufacturer's wholesale price for the total number of dosage units of each form and strength of a prescription drug that the department reports as reimbursed to providers of prescription drugs, provided payments are not due until 30 days following the manufacturer's receipt of utilization data supplied by the department, including the number of

dosage units reimbursed to providers of prescription drugs during the period for which payments are due.

C. Beginning October 1, 1998, the department shall seek to achieve an aggregate rebate amount from all rebate agreements that is 6 percentage points higher than that required by paragraph B of this subsection, provided such rebates result in a net increase in the rebate revenue available to the elderly low-cost drug program. In the event the department is not able to achieve the rebate amount required by this paragraph without compromising the best interest of recipients of the elderly low-cost drug program, it shall report to the joint standing committee of the Legislature having jurisdiction over health and human services matters and the joint standing committee of the Legislature having jurisdiction over appropriations and financial affairs in the First Regular Session of the 119th Legislature.

Upon receipt of data from the department, the pharmaceutical manufacturer shall calculate the quarterly payment. If a discrepancy is discovered, the department may, at its expense, hire a mutually agreed-upon independent auditor to verify the pharmaceutical manufacturer's calculation. If a discrepancy is still found, the pharmaceutical manufacturer shall justify its calculation or make payment to the department for any additional amount due. The pharmaceutical manufacturer may, at its expense, hire a mutually agreed-upon independent auditor to verify the accuracy of the utilization data provided by the department. If a discrepancy is discovered, the department shall justify its data or refund any excess payment to the pharmaceutical manufacturer.

If the dispute over the rebate amount is not resolved, a request for a hearing with supporting documentation must be submitted to the Administrative Hearings Unit. Failure to resolve the dispute may be cause for terminating the drug rebate agreement and denying payment to the

pharmaceutical manufacturer for any drugs.

~~All prescription drugs of a pharmaceutical manufacturer who enters into an agreement pursuant to this subsection that appear on the approved list of drugs must be immediately available and the cost of the drugs must be reimbursed and is not subject to any restrictions or prior authorization requirements.~~ Any prescription drug of a manufacturer that does not enter into an agreement is not reimbursable unless the department determines the prescription drug is essential.

All prescription drugs of a pharmaceutical manufacturer that enters into an agreement pursuant to this subsection that appear on the list of approved drugs under this program must be immediately available and the cost of the drugs must be reimbursed and is not subject to any restrictions or prior authorization requirements, except as provided in this paragraph. If the commissioner establishes maximum retail prices for prescription drugs pursuant to section 2693, the department shall adopt rules for the elderly low-cost drug program requiring the use of a drug formulary and prior authorization for the dispensing of certain drugs to be listed on a formulary. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

Sec. B-2. 22 MRSA §254, sub-§8-A is enacted to read:

8-A. Participation requirement. Beginning January 1, 2001, all manufacturers and labelers of drugs that participate in the Medicaid program under this Title must participate in the drug rebate program under subsection 8. For the purposes of this subsection, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

Sec. B-3. 22 MRSA §3174-Y is enacted to read:

§3174-Y. Prior authorization in Medicaid program

If the commissioner establishes maximum retail prices for prescription drugs pursuant to section 2693, the department shall adopt rules for the Medicaid program requiring additional prior authorization for the dispensing of drugs determined to be priced above the established maximum retail prices. The department shall adopt rules for the Medicaid program requiring additional prior authorization for the dispensing of drugs provided from manufacturers and labelers who do not enter into agreements with the department under section 2681, subsection 3. For the purposes of this section, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

Supreme Court, U.S.
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No. 01-188

In The

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, Commissioner, Maine Department of Human Services, and G. STEVEN ROWE, Attorney General of Maine,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. § 1396 *et seq., prohibits* a state from using authority under that statute to compel drug manufacturers to provide rebates for drugs sold to uninsured Maine residents?

2. Whether the Maine Rx statute, 22 Me.Rev.Stat.Ann. § 2681 *et seq.*, which seeks rebate payments in connection with in-state retail sales of prescription drugs to uninsured Maine residents, violates the dormant Commerce Clause because wholesale transactions in those drugs occur outside of Maine?

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STATEMENT OF THE CASE

The questions presented by petitioner do not merit certiorari review. First, there is no conflict in the lower courts on the question of whether Medicaid prohibits the states from using prior authorization to induce prescription drug manufacturers to negotiate rebate agreements. Congress expressly authorized the states to impose prior authorization on any drug covered by Medicaid, without limitation. Its use in the Maine Rx program does not conflict with Medicaid, and, in fact, advances fundamental Medicaid objectives.

Second, there is no conflict on the question of whether a state law providing for such negotiated rebate agreements would infringe the dormant Commerce Clause. No other state has enacted such a law. Moreover, the well-reasoned opinion of the First Circuit is correct and carefully applies the governing analysis established by this Court's dormant Commerce Clause decisions. Petitioner's dormant Commerce Clause argument relies entirely on cases involving protectionist price-tying statutes. As the First Circuit determined, those cases are inapplicable because the Maine statute does not have the protectionist effect of a price-tying statute.

This facial challenge on a motion for a preliminary injunction is simply premature for certiorari review. The statutory system challenged here has not been implemented in Maine or anywhere else, and petitioner's theories about its possible effects on Medicaid recipients and prescription drug manufacturers require empirical evaluation that is not yet possible. Petitioner's members have not entered negotiations for rebate agreements; the Act's

prior authorization provisions have not been employed; and any impact the program might have on manufacturers remains entirely speculative.

I. The Maine Rx Program

Maine residents without prescription drug insurance coverage often cannot afford to purchase the medicines their doctors prescribe. Maine Rx is a new program designed to give these consumers the benefit of a price discount similar to that enjoyed by consumers covered by private and governmental health plans, which are able to make bulk purchases of drugs. Pharmacies will offer this discount on those drugs that are manufactured by pharmaceutical companies that have elected to participate in the program. Maine will reimburse the pharmacies for giving the discount, and it will pay the pharmacist a modest dispensing fee. 22 Me.Rev.Stat.Ann. § 2681(6)(D), reproduced in the appendix to the petition for a writ of certiorari at 89 (hereinafter "*Pet. App.*"). Maine will fund the program, on a continuing basis, by collecting a rebate payment for each prescription filled from the participating manufacturer. 22 Me.Rev.Stat.Ann. § 2681. *Pet. App.* at 86.

The Commissioner of the Maine Department of Human Services (the "Commissioner" and the "Department") and each manufacturer that elects to participate in the program will enter into negotiations to determine the size of the rebate to be paid, and thus the size of the discount to be offered, for that manufacturer's drugs. 22 Me.Rev.Stat.Ann. § 2681(4). *Pet. App.* at 87. The Act directs the Commissioner to use his "best efforts" to

negotiate Maine Rx rebates that are as generous as those which manufacturers provide when the state purchases their drugs on behalf of Maine's Medicaid recipients. 22 Me.Rev.Stat.Ann. § 2681(4)(B). *Pet. App.* at 88. The Act does not, however, require that this or any other rebate amount be achieved in the rebate negotiations.

A participating manufacturer's assumed obligation to pay a Maine Rx rebate is triggered by the retail sale in Maine of the participating manufacturer's drug to a Maine resident by a Maine pharmacy. The obligation does not depend on where the manufacturer is located or where wholesale transactions involving the manufacturer's products take place. Moreover, the Act does not dictate what manufacturers may charge for their products, and manufacturers may change their prices without any consequences whatsoever. The program only seeks to obtain a rebate, the amount of which is fixed by negotiation (though revisited each year).

Participation in the program is voluntary and twenty-seven non-PhRMA members had agreed to participate before the district court ruled on PhRMA's preliminary injunction motion. *JA* at 144.[1] To be sure, a manufacturer's election not to participate carries certain potential consequences. Chief among these consequences is the mechanism Maine Rx employs to encourage participation. Specifically, the Act instructs the Department to "impose prior authorization requirements in the Medicaid program . . . *as permitted by law*, for the dispensing of

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[1] Citations with the notation "JA" refer to items in the parties' Joint Appendix before the court of appeals.

prescription drugs provided by those manufacturers" that elect not to participate in the Maine Rx program. 22 Me.Rev.Stat.Ann. § 2681(7) (emphasis added). *Pet. App.* at 89-90.

"Prior authorization" is a device found in many public and private health plans and is simply a requirement that the permission of the plan's administrator be obtained by a physician before reimbursement will be allowed for the dispensing of particular drugs. This device, which is an expression of a health plan's purchasing preference for certain drugs, is premised on the economic reality that competing companies market comparable drugs that are often equally effective in treating a given medical disorder. A health plan administrator will typically approve a physician's request to dispense a drug appearing on the plan's prior authorization list upon demonstration that it is in the patient's best interest to do so. Under Maine Rx, the possibility that a drug will be subjected to prior authorization provides an incentive for manufacturers to participate in the program because imposition of a prior authorization requirement may be detrimental to the manufacturer's market share of that drug when adequate therapeutic alternatives exist.

Federal Medicaid law gives broad authority to the states "to subject to prior authorization *any* outpatient drug." 42 U.S.C. § 1396r-8(d)(1)(A) (emphasis added). *Pet. App.* at 78. Medicaid does not dictate, or in any way limit, how a state goes about identifying the specific drugs for

which it will require prior authorization.[2] It also does not mandate criteria to be used in reviewing individual physician requests to prescribe a drug appearing on the prior authorization list.

II. District Court Proceedings

PhMRA filed its complaint and motion for a preliminary injunction on August 10, 2000, one day before the Act's effective date and over four months before the program was to begin. The parties briefed the legal issues raised by the motion without taking discovery, and filed only a few affidavits and a handful of supporting materials with the briefs. In short, this case came up for review as a purely facial challenge to a unique program, with no record of the actual effect the Act may have on manufacturers, Medicaid recipients or eligible consumers.

In its analysis of the preliminary injunction request, the district court construed the Maine Rx program as a price control measure. It determined that although the Act does not discriminate against commerce of other

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[2] As the court of appeals found, the Department has itself proposed administrative rules governing prior authorization under Maine Rx and "aimed at ensuring that Medicaid recipients will have access to needed medications." *Pet. App.* at 12. As the court noted, "the decision to place a drug on the prior authorization list may be made only by the State's Medicaid Drug Utilization Review [DUR] Committee, which exclusively comprises physicians and pharmacists licensed to prescribe or dispense medications in Maine." *Id.*

states, Maine lacks authority over out-of-state manufacturers under this Court's dormant Commerce Clause cases. *Pet. App.* at 64-65. On the Supremacy Clause issue, the district court determined that the Act fails to advance any Medicaid purpose, and that its use of prior authorization – although expressly authorized by Congress – was nonetheless an obstacle to Congress' objectives in enacting Medicaid. *Pet. App.* at 68. The district court granted the preliminary injunction on October 26, 2000.

The Maine Rx program has been in limbo since that date. Although several companies have signed rebate agreements, no PhRMA member company has even entered into negotiations. No company has yet paid a rebate, and no drug has been subjected to prior authorization under the Act. Of course, eligible consumers have not yet received any Maine Rx discounts.

III. Decision of the First Circuit

A unanimous panel of the First Circuit[3] reversed the district court and vacated the temporary injunction. *Pet. App.* at 29. As the district court did, the court of appeals focused its attention on the "likelihood of success" prong of the preliminary injunction calculus. Before reaching the principal issues, however, the court of appeals determined that PhRMA has prudential standing to lodge its

[3] Although petitioner did not object prior to the ruling, it now notes that the panel contained no active judge of the First Circuit. *Pet.* at 6. All three judges on the panel are federal judges – two district court judges and one senior circuit judge. The composition of the panel was proper pursuant to 28 U.S.C. § 46(b), and PhRMA cannot suggest otherwise.

Supremacy Clause challenge, and that it may invoke the rights of Medicaid recipients it claims are disadvantaged by the Act. *Pet. App.* at 7-8. Turning to PhRMA's preemption argument, the court of appeals observed that Congress expressly authorized the states to impose prior authorization on any prescription drug covered by a state Medicaid program. The court noted that the only limits on that express grant of power are requirements that the state respond quickly when a patient presents a prescription subject to prior authorization, and that a 72-hour supply be provided in emergencies. *Pet. App.* at 11. PhRMA does not contend that the Act fails to meet these requirements.

The court of appeals then rejected PhRMA's argument that the Maine Rx program must be preempted by Medicaid because it fails to advance any "Medicaid purpose." *Pet. App.* at 12. First, the court determined that the mere failure to advance a federal program is not the proper test for applying the "strong medicine" of preemption. *Pet. App.* at 13. Second, the court found that the Maine Rx program does, in fact, advance the goals of Medicaid by keeping people healthy and preventing them from falling into poverty and dependence on Medicaid and other programs. *Pet. App.* at 13-14. The First Circuit "perceive[d] no conflict between the Maine Act and Medicaid's structure and purpose," the proper analysis of PhRMA's implied conflict preemption claim. *Pet. App.* at 11.

The court of appeals also rejected PhRMA's claim that the Maine Rx program would interfere with the best interests of Medicaid recipients, finding that "at this point in the proceedings, [there is an] insufficient basis

for concluding that the Maine Act, on its face, controverts" such interests. *Pet. App.* at 15. In particular, the court found that "there is no evidence that the prior authorization procedure is likely to foreclose a patient from receiving a necessary drug." *Pet. App.* at 16. Recognizing that the picture may change as the Act is implemented, the court noted that PhRMA could readily renew its challenge if actual experience with the program showed some tangible interference with the objectives of Medicaid. *Pet. App.* at 17.

The First Circuit went on to dispose of PhRMA's contention that the Maine Rx rebate provisions infringe the dormant Commerce Clause. The court of appeals applied a three-step analysis to the dormant Commerce Clause claim. First, it determined that the statute was not subject to a *per se* analysis because it does not have an "extraterritorial reach." *Pet. App.* at 20-24. It next determined that strict scrutiny did not apply because the statute was not enacted for a discriminatory purpose and does not have a discriminatory effect. *Pet. App.* at 24-25. Finally, the court of appeals determined that the Act regulates evenhandedly and any effect it may have on interstate commerce is merely incidental. *Pet. App.* at 25. Applying the balancing test articulated by this Court in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), the court of appeals determined that the impact on manufacturers is both speculative and not the kind of effect the dormant Commerce Clause is meant to preclude. *Pet. App.* at 26-27. Accordingly, the court of appeals reversed the district court decision in its entirety and vacated the preliminary injunction. *Pet. App.* at 29.

The First Circuit denied petitioner's request for a panel rehearing and for a rehearing *en banc* but temporarily stayed its mandate pending PhRMA's petition for a writ of certiorari. *Pet. App.* at 54-55.

REASONS FOR DENYING THE WRIT

I.

There Is No Compelling Reason To Review the Decision of the Court of Appeals.

The questions presented by the First Circuit's decision do not warrant certiorari review by the Court. As a preliminary matter, however, it is necessary to correct the framing of the questions presented in the petition.

Under this Court's jurisprudence in the area of "conflict preemption" under the Supremacy Clause, a state's exercise of its sovereign powers in enacting legislation is legitimate unless constitutionally permissible federal legislation on the subject clearly prohibits the state effort, either expressly or by implication. *Gade v. National Solid Waste Management Association*, 505 U.S. 88 (1992). The question which PhRMA's preemption challenge to the Act presents is therefore not whether the Medicaid statute *allows* use of prior authorization in the manner contemplated by Maine Rx. *Pet.* at i. Rather, the proper constitutional test, and question presented, is: Whether the federal Medicaid statute *prohibits* a state from using

authority under that statute to compel drug manufacturers to provide rebates for drugs sold to uninsured Maine residents?[4]

Likewise, petitioner frames the dormant Commerce Clause question around the unwarranted assumption that the rebate provision is either a "tax" or a "regulation." *Pet. App.* at i. Maine, however, is not using its taxing or regulatory power. The State is only using its purchasing power in Medicaid to induce manufacturers to discount their products when purchased by Maine residents without insurance. The negotiated agreements establishing those discounts are not a tax or a regulation of interstate commerce. Yet, by using these terms to mischaracterize the Maine Rx program, PhRMA proposes a question that is improperly argumentative. SUP. CT. R. 14.1.(a) The question raised by PhRMA's dormant Commerce Clause challenge, rather, is: Whether Maine Rx, 22 Me.Rev.Stat.Ann. § 2681 *et seq.*, which seeks rebate payments in connection with in-state retail sales of prescription drugs to uninsured Maine residents, violates the dormant Commerce Clause because wholesale transactions in those drugs occur outside of Maine?

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[4] Indeed, petitioner's assertion of a conflict between the First Circuit's decision here and a recent decision of the District of Columbia Circuit is internally consistent only because of the use of the wrong verb ("allows") in PhRMA's proposed question presented. As is demonstrated at pages 11-12 below, the claim of a conflict does not survive even a cursory reading of the two court of appeals opinions.

A. There is No Compelling Reason to Review the Supremacy Clause Ruling.

1. The First Circuit Decision Does Not Conflict With the Decision of Other Federal Circuit Courts.

As the parties and the court of appeals agreed, this is a Supremacy Clause case of the "implied conflict preemption" variety. *Pet. App.* at 9. Thus far, no statute bearing material similarities to Maine Rx or raising the same Supremacy Clause concerns has been the subject of litigation outside of the First Circuit. There is therefore no disarray in the law or lower court development of jurisprudence on this issue requiring this Court's attention now.

The only case that petitioner suggests is in conflict with the present one, *PhRMA v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001), raises no Supremacy Clause question. It is only a statutory construction case. The issue before the District of Columbia Circuit was whether the federal Department of Health and Human Services exceeded its statutory authority when it approved an experimental "demonstration" project for Vermont's Medicaid program. *Id.* at 222-23. Resolution of this issue turned exclusively on the question of what the term "payment" means in the provision of the Medicaid statute which requires that participating manufacturers provide rebates on drugs for which "payment was made under the state plan." *Id.* at 223-26.

Although even a cursory reading of the two opinions reveals that no conflict is present, PhRMA desperately seeks to conjure up one. It voices the superficial, and

imprecise, observation that the demonstration project at issue in *Thompson* and the Maine Rx program each employ the "leverage of Medicaid." *Pet.* at 13. But two appellate decisions, addressing different legal questions raised by two different programs, do not create a conflict of the sort to be resolved on certiorari review simply because one program is struck down while the other is upheld or because they each implicate different aspects of Medicaid.

2. The Court of Appeals' Resolution of the Supremacy Clause Question is Consistent With this Court's Precedents.

Not only did the First Circuit answer a question that is different from both the question answered in *Thompson* and the "question presented" which PhRMA now offers, but the lower court answered it in a manner consistent with bedrock principles of constitutional law as explained by this Court. First and foremost among those principles is the assumption "that the historic police powers of the States [are] not to be superceded by the Federal Act unless that [is] the clear and manifest purpose of Congress," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), or, in the words of the First Circuit, preemption is "strong medicine . . . not casually to be dispensed." *Pet. App.* at 10.

Following strictly the approach mandated by *Gade v. National Solid Waste Management Association*, 505 U.S. 88 (1992), the court of appeals conducted an exhaustive examination of the language, structure, and "discernable objectives" of the federal Medicaid statute. *Pet. App.* at

10-17. This search uncovered nothing suggesting that Congress intended to prohibit the use of a state's broad prior authorization discretion to accomplish a goal shared by both Medicaid and Maine Rx – promoting the health of Maine's people by making prescription medicine readily available to citizens whose "income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396; *Pet. App.* at 13. *See also* 22 Me.Rev.Stat.Ann. § 2681(1) (Maine Rx program goals); *Pet. App.* at 86.

The First Circuit also reviewed the scant record developed on the motion for preliminary injunctive relief and found that PhRMA had failed to establish, as is required in order for its facial challenge to succeed, that implementation of Maine Rx "will inflict inevitable or even probable harm on Medicaid patients or their providers." *Pet. App.* at 16. While this finding is indeed contrary to that of the district court, the conclusions which may be drawn from the affidavits submitted by the parties is not an issue meriting review by this Court. *See* R. Stern, E. Gressman, S. Shapiro & K. Geller, *Supreme Court Practice*, § 4.17 (7th ed. 1993).

3. Substantial Questions Exist As to Whether PhRMA Has Standing to Bring a Supremacy Clause Challenge to Maine Rx.

Another problem with this petition is that PhRMA, a pharmaceutical industry trade association, may not have prudential standing under this Court's "zone of interests" test to bring a claim that Maine Rx is preempted by Medicaid. Standing appears to be wanting because

PhRMA does not seek to vindicate an interest it holds which is even arguably within the zone of interests protected or regulated by the allegedly preemptive Medicaid statute. *National Credit Union Administration v. First National Bank & Trust Co.*, 522 U.S. 479, 492 (1998). PhRMA's interest here is merely a desire to protect the market share of its members' products from the effect of prior authorization. Medicaid does not protect this interest and PhRMA does not argue otherwise.[5]

The First Circuit did not look, however, to the interests protected by Medicaid to find that PhRMA satisfies the prudential standing requirement. Instead, the court held that the zone of interests test is satisfied because PhRMA's interests are protected by the Supremacy Clause itself. *Pet. App.* at 7. This was error because, unlike other provisions of the constitution, the Supremacy Clause cannot itself provide the sort of interest which satisfies the zone of interests test for the simple reason that the Supremacy Clause does not, by its own force, create any federal rights. As explained by the Court in *Golden State Transit v. City of Los Angeles*, 493 U.S. 103, 107 (1989), a party may not bring an action under 42 U.S.C.

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[5] The requirement that Medicaid funds be expended only on those drugs for which manufacturers have agreed to sell at a discount (a discount collected through a rebate payment), is not, as PhRMA suggested below, a form of regulation of the pharmaceutical industry. 42 U.S.C. § 1396r-8(a)(1). *Pet. App.* at 73. Nothing in federal law *requires* a manufacturer to provide a Medicaid rebate in the first instance. Manufacturers do so only after electing to take advantage of the sizable market for their products created by Medicaid. Offering a discount in order to gain entry into this market can hardly be viewed as a form of "regulation" of the drug industry.

§ 1983 for violation of the Supremacy Clause for the fundamental reason that the Supremacy Clause does not itself confer federal rights. *See also Dennis v. Higgins*, 498 U.S. 439, 449 (1991) (noting that the question of whether a particular constitutional provision confers a federal right enforceable under § 1983 is related to the question of whether that constitutional provision protects an interest sufficient to satisfy the zone of interests test). In fact, if the Supremacy Clause alone could provide the basis for prudential standing, as the court of appeals held, then any person seeking to bring a Supremacy Clause challenge to a state statute would have prudential standing no matter how far removed that person is from the interests protected or regulated by the allegedly preemptive federal statute. Yet, the decision below on the standing issue diminishes the zone of interests test in precisely this fashion.

PhRMA's standing to raise vicariously the claim of a Medicaid recipient, that Maine Rx infringes his or her interest in obtaining drugs free from prior authorization requirements, is further suspect because it is questionable whether a Medicaid recipient could, in fact, bring such a claim. *See Westside Mothers v. Haveman*, 133 F.Supp.2d 549 (E.D. Mich. 2001) (Medicaid recipients may not bring an action against state officials to enforce Medicaid's requirements because Medicaid was enacted pursuant to Congress' "spending power" under Article I, section 8, of the Constitution and thus its requirements are not the "supreme Law of the Land."). This issue of federalism, and the prudential standing issue to which it is related, would have to be addressed by this Court if it were to

accept this case for review. These issues were not, however, the object of significant attention by the First Circuit. Their presence here, however, makes this case a poor vehicle for review in this Court of the constitutional issues PhRMA seeks to raise.

B. There Is No Compelling Reason To Review the Dormant Commerce Clause Ruling.

1. The First Circuit Decision Does Not Conflict With the Decisions of Other Federal Circuit Courts.

The First Circuit's decision upholding Maine Rx against PhRMA's dormant Commerce Clause challenge does not conflict with the decision of any other Circuit. Indeed, petitioner does not allege such a conflict. Certiorari review of the dormant Commerce Clause question is therefore not warranted [6]

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[6] Petitioner cites several lower court cases without claiming that they represent a conflict in the circuits. *See Pet.* at 14, citing *Dean Foods Co. v. Brancel*, 187 F.3d 609 (7th Cir. 1999) (invalidating Wisconsin milk volume discount statute as applied to transactions taking place at Illinois milk processor); *Louisiana Dairy Stabilization Bd. v. Dairy Fresh Corp.*, 631 F.2d 67 (5th Cir. 1980) (invalidating milk processing regulation that required payment of fees to protect Louisiana dairy industry); *Schwegmann Bros. Giant Super Mkts. v. Louisiana Milk Comm'n*, 365 F.Supp. 1144 (M.D. La. 1973), *aff'd mem.* 416 U.S. 922 (1974) (invalidating Louisiana minimum price regulation as applied to wholesale transaction in Tennessee). *Dean Foods* and *Schwegmann* involved price control statutes that directly constrained the price in transactions taking place outside the state's borders. *Louisiana Dairy Stabalization Bd.* involved a fee system that was applied to out-of-state transactions in order to protect in-state milk producers. None of these cases conflicts with the First Circuit's decision because the Maine Rx negotiated rebates agreements simply do not control prices extraterritorially and do not protect in-state industries.

2. Petitioner's Argument that the Maine Rx Program Is A Tax Was Not Part of the Court of Appeals' Decision Under Review.

Petitioner contends that the negotiated rebates are actually a tax and should be enjoined under *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977). *Pet.* at 19-21. This Court need not review that argument because it was not part of the decision below. *Pet. App.* at 27, n.11. Moreover, the question of whether the manufacturers have a substantial nexus with Maine, as is required of a tax under *Complete Auto*, would be a heavily fact-bound inquiry into the extent to which retail sales through the Maine Rx program would be attributed to the employees, advertising and other activities of the manufacturers within Maine. *Complete Auto* at 277-78. There is no record evidence on that question. In any event, if the Maine Rx rebate *is* a "tax," petitioner has brought its case in the wrong forum. The federal district court does not have jurisdiction to enjoin a state tax. Tax Injunction Act, 28 U.S.C. § 1341.

3. The First Circuit's Decision Is Consistent With the *Baldwin/Brown-Forman/Healy* Decisions.

The court of appeals correctly determined that this Court's extraterritorial price control cases – *Healy v. The Beer Institute*, 491 U.S. 324 (1989), *Brown-Forman Distillers*

Corp. v. New York State Liquor Auth., 476 U.S. 573 (1986), and *Baldwin v. G.A.F. Seelig*, 294 U.S. 511 (1935) – do not support petitioner's dormant Commerce Clause claim. *Pet. App.* at 20-24.[7] Each of these cases involved state statutes that had the practical effect of directly regulating extraterritorial prices, locking the in-state price to those charged in another state. Tying prices in one state to those in another was incompatible with the Commerce Clause because it warped the interstate marketplace.

The Maine Rx statute does not have that effect, either directly or indirectly. Simply put, it does not tie in-state prices to pricing elsewhere. It does not constrain manufacturers' pricing freedom, and does not interfere with economic forces. The Maine Rx system is a program of quarterly rebate payments determined by the volume of in-state retail sales multiplied by a rebate amount that is separately negotiated with each manufacturer. It does not include a wholesale price control mechanism, either directly or indirectly, and does not have that "practical effect." *Healy*, 491 U.S. at 337.[8] Maine simply has not

[7] The Court of Appeals correctly applied the analysis of *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), finding that the Act "regulate[s] evenhandedly" and any "incidental effects on interstate commerce" are "clearly outweigh[ed by] the putative local benefits." *Pet. App.* at 25-27.

[8] The "critical consideration" in dormant Commerce Clause review is "the overall effect of the statute on both local and interstate activity." *Brown-Forman*, 476 U.S. at 579. Unlike the price-tying cases, the practical effect of the Maine Rx statute is not obvious in this facial challenge.

"prescribe[d] the rule by which commerce is to be governed." *Gibbons v. Ogden*, 22 U.S. 1 (9 Wheat.) (1824). This fundamental structural difference renders *Baldwin*, *Brown-Forman* and *Healy* inapposite.[9]

Equally significant, the rationale underlying *Baldwin*, *Brown-Forman* and *Healy* does not apply here. Each of those cases relied on the core dormant Commerce Clause value of an open competitive market, free from the discriminatory legislation of the several states. Petitioner, however, does not even allege that the Act has any such anti-competitive or discriminatory effect. As the Court noted in *Brown-Forman*, "a State may seek lower prices for its consumers, [so long as it does] not insist that producers or consumers in other States surrender whatever competitive advantages they may possess." 476 U.S. at 580. That is precisely what Maine has done.

Petitioner invites the Court to expand the dormant Commerce Clause far beyond its essential purpose of ensuring that the interstate market is unencumbered by

[9] Those cases are inapposite for an additional reason. In each case the state sought to sanction non-compliant businesses, whereas the only consequence to manufacturers who do not enter Maine Rx rebate negotiations is that their sales to the Maine Medicaid program may decline somewhat. Maine, therefore, is using its power as a market participant, not its regulatory authority, and the dormant Commerce Clause is not implicated. *See White v. Massachusetts Council of Construction Employers, Inc.*, 460 U.S. 204 (1983); *Reeves, Inc. v. Stake*, 447 U.S. 429 (1980); *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794 (1976). The Court of Appeals rejected respondents' market participation argument. *Pet. App.* at 20.

discriminatory state legislation.[10] *See CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69, 87 (1987) ("[t]he principal objects of dormant Commerce Clause scrutiny are statutes that discriminate against interstate commerce"); Donald Regan, *The Supreme Court and Economic Protectionism: Making Sense of the Dormant Commerce Clause*, 84 Mich. L. Rev. 1091, 1092 (1986) (in dormant Commerce Clause cases "the Court has been concerned exclusively with preventing states from engaging in purposeful economic protectionism"). Only discriminatory statutes or those that control the terms of trade in other states have been invalidated on a *per se* basis. *Brown-Forman*, 476 U.S. at 578-79.[11] The dormant Commerce Clause has never been a categorical ban on state statutes with incidental extraterritorial effects. *See CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69 (1987) (upholding state anti-takeover law that applied to extraterritorial transactions); *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 126-28, *reh. denied sub nom., Shell Oil Co. v. Governor of Maryland*, 439 U.S. 884 (1978) ("The fact that the burden of a state regulation falls on some interstate

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[10] PhRMA raises the specter of states taxing oil from Texas or computer chips from California. *Pet.* at 17 n.6 Such blatantly discriminatory legislation is a far cry from the non-discriminatory negotiated rebate agreements at issue here.

[11] Indeed, in the "price-tying" section of its petition PhRMA acknowledges that the dormant Commerce Clause cases apply the *per se* rule only when a statute requires a manufacturer to "factor the in-state price ramifications into their pricing calculations," which the Act does not. *Pet.* at 18-19. As explained below, although that section of the petition correctly depicts the dormant Commerce Clause, it fundamentally misrepresents the Act.

companies does not, by itself, establish a claim of discrimination against interstate commerce. . . . The Commerce Clause protects the interstate market, not the particular interstate firms, from prohibitive or burdensome regulations"). The dormant Commerce Clause simply does not prohibit state laws that affect the profitability of out-of-state entities whose products are consumed within the State.[12]

Petitioner relies heavily on its mischaracterization of the actual language of the Act. Petitioner contends that the Act "specifies that the rebate required of manufacturers shall equal or exceed the rebates required around the country under Medicaid and other federal programs. 22 Me.Rev.Stat.Ann. § 2681(3), (4)." *Pet.* at 18. The actual language of the cited provisions, however, belies petitioner's assertion, in two ways. First, § 2681(4) provides that the amount of the rebates is to be *negotiated* between the Commissioner and each separate manufacturer. No minimum rebate is "specified." As Judge Keeton's

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[12] Petitioner asserts that drug manufacturers' profits constitute "ancillary terms" of the wholesale transaction, *Pet.* at 17, and that therefore any state regulation that reduces profits is a forbidden regulation of interstate commerce. But "profit" is a concept related to the overall operations of an entire company; it is not a "term" of the sale transaction between the manufacturer and its customer. The distinction is fundamental. Regulating the terms of wholesale transactions would interfere with the laws of supply and demand that the dormant Commerce Clause evolved to protect. But countless state laws and regulations affect retail transactions in ways that reduce the profits of companies located elsewhere, and no one suggests that such laws automatically violate the Commerce Clause.

concurring opinion emphasized, the rebate provision "is *not* a statutory mandate." *Pet. App.* at 42. (emphasis in original). Petitioner's disagreement with the court of appeals' interpretation of a state statute is of little national interest and does not warrant this Court's review.

Equally important for dormant Commerce Clause purposes is that, while the Commissioner is directed to use his "best efforts" to negotiate rebates approaching those offered through other public assistance programs, the Act simply does not tie the rebates to those amounts or to any other index. Manufacturers may negotiate rebate agreements unrelated to any other price, leaving them free to change prices anywhere without regard to the Maine Rx rebate agreement.[13] Unlike *Baldwin*, *Brown-Forman* and *Healy*, Maine simply has not "establish[ed] a . . . scale of prices for use in other states," directly or indirectly. *Baldwin*, 294 U.S. at 528.

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[13] The Maine legislature understood that there would be real negotiations between the Commission and the manufacturers, and that there was no guarantee that manufacturers would agree to substantial rebates. For example, if the legislature believed it had enacted mandatory rebates, as PhRMA alleges, the separate price control provisions would have been superfluous. *See* 22 Me.Rev.Stat.Ann. § 2693(1)(B). *Pet. App.* at 96. Those retail price controls take effect on July 1, 2003, but only if the rebates negotiated by the Commissioner are insufficient. *Id.* The negotiation process was halted by this lawsuit, and the size of the rebates manufacturers would have agreed to had the process continued remains a matter of speculation.

II.

The Context In Which the Issues Are Framed in this Case Make it an Inappropriate Vehicle for Certiorari Review

Petitioner prematurely seeks certiorari review of its facial challenge to Maine Rx at the preliminary injunction stage. The court of appeals, however, recognized that the present posture of this case, together with the particular brands of constitutional arguments PhRMA asserts, makes it difficult to assess what impact, if any, Maine Rx will have on Medicaid patients and on interstate commerce. As the court noted, "[b]ecause this is a facial challenge to a statute, PhRMA has a difficult burden of showing that Medicaid recipients will be harmed by the Maine Rx Program." *Pet. App.* at 15. The court further recognized that the affidavits submitted in connection with the preliminary injunction motion, "along with other materials in the record, fall short of establishing that the Act will inflict inevitable or even probable harm on Medicaid patients." *Id.* at 16. Agreeing that a more robust factual record would permit review of PhRMA's claims without the need for prediction or speculation, the court specifically provided that its "decision is without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the prior authorization requirement "as applied." *Id.*[14]

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[14] Respondents take issue with PhRMA's suggestion that to wait for an "as applied" challenge would be to conduct outrageous "human experimentation" on patients. *Pet.* at 10. Certainly PhRMA's drug manufacturer members cannot dispute

The possible scope of a future "as applied" review of PhRMA's Commerce Clause challenge was also noted by the court. For instance, the Commissioner's negotiations with manufacturers for rebate agreements may, in practice, "become coercive or otherwise inappropriate" so as to create "an issue that needs to be revisited once the Act takes effect." *Pet. App.* at 23. Similarly, the balancing required by *Pike*, 397 U.S. at 142, of the local benefits of Maine Rx against any burden it might place on interstate commerce, can be more concrete and searching once the statute has been implemented. Thus, although the court held that, "[f]or now, it is enough to say that the Act survives the facial challenge under the dormant Commerce Clause," it welcomed a future, as applied challenge. *Pet. App.* at 27. The court described the problems posed by deciding this case in its present posture: "[i]t is necessary to recognize the difficulty in foreseeing what events actually will occur from the enforcement of this Act, which admittedly makes the *Pike* balancing test more challenging to apply. We are forced to balance the *possible* effects, instead of the *actual* effects of the statute in action." *Id.* The same considerations concerning the present posture of this facial challenge to Maine Rx that informed the approach of the court of appeals undermine this petition.

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that making life-saving prescription drugs more available to those least able to afford them – the goal of Maine Rx – will promote rather than jeopardize the health of Maine's citizens. It is also beyond dispute that whichever medicine Medicaid recipients receive, it will already have been proven safe and efficacious through appropriate clinical trials.

III.

Petitioner's Characterization of the Need For Immediate Review by this Court Is Overstated.

Maine is the only state to have enacted a statute which uses the Medicaid prior authorization discretion to encourage manufacturer rebates to help lower prescription drug prices for the uninsured. And, it is also the only state to use manufacturer rebates to fund an entirely state-run public benefits program. While Maine's legislation may well have sparked a healthy debate regarding prescription drug programs in other states, PhRMA mischaracterizes the imminence of the revolution it fears.

The handful of state proposals mentioned by PhRMA is hardly a groundswell. For example, the Alabama bill discussed at length by petitioner had already failed by the time PhRMA filed its petition. *See National Conference of State Legislatures, 2001 Prescription Drug Discount, Bulk Purchasing, and Price-related Legislation*, at http://www.ncsl.org/programs/health/drugdisc01.htm (updated August 20, 2001). Proposals in other states mentioned in the petition had either failed to win enactment (Arkansas; Minnesota; Oregon) or had been replaced by legislation lacking the prior authorization mechanism at issue here (Louisiana). *Id., see also* H.B. 2057, 2001 Reg. Sess. (La. 2001) (substituted for H.B. 1089). As one of petitioner's spokespersons, an assistant general counsel to PhRMA, recently said, "I'm not sure that Maine is heading a parade because I'm not sure there is a parade behind them." Francis X. Quinn, *Maine leads quest for cheaper drugs, but is anyone following?*, Associated Press

(AP) Newswires, August 11, 2001, at 1. *See also* Francis X. Quinn, *Maine in lead in drug-cost policy / But example may be too hard to follow for many other states*, Houston Chronicle, August 12, 2001, 2001 WL 23620764, at 1-2.

In addition, the particular constitutional problems alleged in PhRMA's challenge to Maine Rx – federal preemption and the dormant Commerce Clause – are both capable of being and may be resolved by Congress. Federal drug price regulation, pursuant to Congress' Commerce Clause powers, could be made to preempt statutes such as Maine Rx. Indeed, it appears likely that the federal government will be making fundamental changes in this area of public policy soon. On July 26, 2001, the Secretary of the Department of Health and Human Services testified that his agency is creating and promoting new Medicare Rx discount programs that are strikingly similar to the Maine Rx program. *Medicare Modernization: Examining the President's Framework for Strengthening the Program*, Subcomm. On Health of the House Comm. on Energy and Commerce, 107th Cong. (July 26, 2001) (Testimony of Tommy Thompson, Secretary, Dept. of Health and Human Services), http://energycommerce.house.gov/107/hearings/07262001Hearing339/Thompson549.htm at 6 (last visited August 22, 2001). According to Secretary Thompson, Medicare beneficiaries will no longer have to "pay the full cost of their medications out-of-pocket" because they "will have access to greater bargaining power," under the new federal programs. And, according to the Secretary, this program is being implemented even while "Congress debates Medicare reform and the creation of a prescription drug benefit." *Id.* Such imminent action by the federal government

to make prescription drugs more accessible to those least able to afford them may ultimately moot any national significance of Maine's foray into the field.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

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REPLY TO BRIEF IN OPPOSITION

Maine proposes to compel out-of-state drug manufacturers that sell their products to wholesalers outside Maine to pay the state each time their products are sold by retailers to Maine residents. To secure compliance, Maine threatens those manufacturers with restrictions on Medicaid patient access to (and hence sales of) the manufacturers' drugs if they do not pay these subsidies for non-Medicaid populations in Maine. The constitutional and statutory defects of the "Maine Rx" program are ripe for review by the Court, and review at this time is of national importance as states around the country consider similar programs of their own.

I. The Maine Act Is Facially Defective and Its Immediate Consequences Warrant Review at This Time.

Contrary to Maine's argument that review by the Court is premature, the issues in this facial challenge are fully joined and ready for this Court's consideration. No further factual development is required. The Maine Rx program is not voluntary and its effects are not hypothetical: it regulates the terms of out-of-state prescription drug sales, in violation of the Commerce Clause, and its enforcement tool—imposing obstacles to drug coverage for Medicaid beneficiaries, in order to secure price discounts for individuals outside Medicaid—necessarily interferes with the federal Medicaid program.

A. The Maine Rx Program Is Mandatory.

Maine suggests that Maine Rx is merely a "voluntary" subsidy program for Maine's citizens in which out-of-state drug manufacturers may "elect[] to participate," Opp. 2, 3, and that this Court's attention would be premature because

the terms of manufacturers' participation have yet to be "negotiated."

Maine's characterization of the Act is inaccurate. Having declared manufacturers' prices to be "excessive" (App. 101), the Act by its terms requires manufacturers to enter into rebate agreements, and penalizes them severely if they refuse to pay the rebates sought by the state. Simply put, there is nothing to "negotiate." The Maine Rx program is not hortatory but a direct exercise of the state's regulatory authority. To illustrate:

- The Act directs that manufacturers "shall *enter into*" rebate agreements with the state. 22 Me. Rev. Stat. Ann. § 2681(3) (emphasis added). The Act does not invite manufacturers to negotiate rebate agreements; it requires manufacturers to *sign* them.
- The Act candidly speaks of the "rebate *required* from the manufacturer," and explains, for example, that a Maine Rx agreement "*must require* the manufacturer to make [a] rebate payment[] to the State" on a regular schedule. 22 Me. Rev. Stat. Ann. § 2681(3),(4) (emphasis added).
- Any manufacturer that refuses to enter into a rebate agreement faces the sanction of "prior authorization" requirements for their drugs. 22 Me. Rev. Stat. Ann. § 2681(7). The Court of Appeals itself acknowledged that participation in the Maine Rx program is "coerce[d]" by the economic "'hammer' or 'force'" of prior authorization. App. 16-17.

Maine Rx rebates are "voluntary," Opp. 3, only in the sense that manufacturers can disregard the direct statutory command to enter into rebate agreements if they are willing to suffer the serious penalty of prior authorization. By this reasoning, no legislative command is ever compulsory, because all legislative commands—from the obligation to pay taxes to the prohibition on assault—may be ignored as

long as the offender is willing to suffer the consequences. But the ability of a regulated entity to disregard the law does not change the Act from a regulation to an invitation. It does not immunize the Maine Rx program from constitutional and statutory challenges.

B. Petitioner's Claims Are Ripe for Review.

There is nothing interlocutory about the First Circuit's ruling on PhRMA's facial challenges to Maine's statute under the Supremacy Clause or the Commerce Clause. The First Circuit's ruling that Maine may restrict Medicaid patient access to the drugs of manufacturers who do not pay for Maine Rx is final. So too is its ruling that Maine may require out-of-state manufacturers who do not sell their drugs to Maine consumers to subsidize discounts for those consumers. Moreover, no further factual development is needed to test the validity of these rulings.

The imposition of prior authorization requirements—however they are implemented—will necessarily impede the flow of Medicaid benefits to Medicaid recipients. The First Circuit suggested that medical harm to Medicaid patients must be shown in order to establish that Maine Rx interferes with the Medicaid program, and that evidence of such harm should be presented in an "as applied" challenge. App. 16. That holding was mistaken. The courts need not await actual harm to Medicaid patients before addressing PhRMA's preemption challenge. PhRMA has demonstrated that the Act will necessarily constrain the benefits provided for by Congress, for purposes unrelated to Medicaid. That showing is sufficient to justify this Court's review of the Act.

Because of the state's efforts to raise funds for the non-Medicaid Maine Rx program, drugs that previously were covered routinely by Medicaid and available to Medicaid patients and doctors without hindrance will now be more difficult to obtain. Although the state may ultimately

approve a given prescription, the doctor will first have to undertake the burden of making a request to state Medicaid officials and providing written documentation to justify the need for that prescription, for reasons having nothing to do with the safety or economics of the Medicaid program itself. In many cases, the doctor may simply avoid the procedural burden and prescribe second-choice medications instead.

Thus while Respondents might dispute whether all noncompliant manufacturers' drugs will be subject to prior authorization, and whether Medicaid patients ultimately will be refused medically necessary drugs, Opp. 4, 8; App. 14-16, they cannot contest that the imposition of the prior authorization procedure in and of itself restricts Medicaid patient and doctor access to the listed drugs, and does so for purposes unrelated to Medicaid. In the words of the district court, while "the parties disagree on the severity of the obstacle," prior authorization "*is* an obstacle." App. 68 (emphasis added). The very fact that the Act relies on the threat of prior authorization to force manufacturers to pay the required rebates is compelling evidence of its effects.

Accordingly, no further factual development or "as applied" litigation is necessary and PhRMA's facial claims are ripe for review. The Court should disregard any suggestions for delay.

II. The Maine Act Is Preempted by the Federal Medicaid Statute.

A. PhRMA Has Standing To Challenge Maine's Interference with the Federal Medicaid Program.

Maine does not dispute that PhRMA meets Article III standing requirements for its Commerce and Supremacy Clause challenges: PhRMA members are immediately threatened with injury that is both directly attributable to the Maine Rx program and addressable by the courts. *See*

Assoc. Gen. Contractors v. Jacksonville, 508 U.S. 656, 663-64 (1993).

However, Maine renews its claim, raised for the first time on appeal,[1] that PhRMA lacks prudential standing to advance its preemption challenge to the Maine Rx program, suggesting that PhRMA's members are not within the "zone of interests" of the Medicaid statute. Opp. 13-14. The First Circuit rejected that argument, explaining—consistent with other Courts of Appeals—that PhRMA's prudential standing is grounded in the Supremacy Clause. App. 6-8, citing *St. Thomas-St. John Hotel & Tourism Ass'n. v. Virgin Islands*, 218 F.3d 232, 241 (3d Cir. 2000) (state law can be "preempted by federal law even when the federal law secures no individual substantive rights for the party arguing preemption"). PhRMA is not attacking the Medicaid statute or its implementation, and need not be within that statute's "zone of interests." PhRMA members are undeniably regulated by the statute that it does challenge—namely, the Maine Act. A party regulated by a state statute that conflicts with a governing federal law has a direct cause of action under the Supremacy Clause. *See, e.g.*, *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624 (1973) (considering a preemption claim without reference to any substantive federal rights or private right of action on the part of the plaintiff).[2]

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[1] Maine should be deemed to have waived any prudential standing objection, as PhRMA argued below. *See Pershing Park Villas Homeowners Assoc. v. United Pacific Ins. Co.*, 219 F.3d 895, 899 (9th Cir. 2000); *Lindley v. Sullivan*, 889 F.2d 124, 129 (7th Cir. 1989); *but see Community First Bank v. National Credit Union Admin.*, 41 F.3d 1050, 1053 (6th Cir. 1995).

[2] Maine also suggests that PhRMA's right to advance a Supremacy Clause claim depends on whether it claims violations of federal rights enforceable under 42 U.S.C. § 1983. Opp. 14-15. No such link exists; courts routinely entertain preemption

Even if prudential standing under the federal Medicaid statute were an additional requirement for a preemption challenge, PhRMA meets that test. PhRMA's members participate in the Medicaid drug assistance program, the terms of which (such as the calculation of rebate amounts and obligations to supply data) directly regulate manufacturers. *See generally* App. 73-84.

More important, the Medicaid statute also protects manufacturers by setting forth the terms of the *quid pro quo* of their participation in the Medicaid drug program: manufacturers pay rebates to Medicaid, in exchange for which their drugs are made available to Medicaid patients for purchase with Medicaid funds. The Medicaid drug coverage obligation is subject to only limited exceptions. *See* App. 79-81. By conditioning access to Medicaid coverage on Maine Rx payments, Maine has unilaterally reduced the "benefit" of the manufacturers' Medicaid bargain. The terms of that delicately balanced bargain were set out by Congress in the Medicaid statute,[3] and both

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claims directly under the Supremacy Clause. *See, e.g., Western Air Lines, Inc. v. Port Auth. of N.Y. and N.J.*, 817 F.2d 222, 225-26 (2d Cir. 1987) (considering Supremacy Clause claim absent a direct right of action under federal statute); *Maryland Pest Control Ass'n v. Montgomery County*, 884 F.2d 160, 162-63 (4th Cir. 1989) (per curiam) (plaintiffs prevailed on Supremacy Clause claim but lacked claim under § 1983 to support § 1988 attorneys fees) (citing other cases), *cert. denied*, 494 U.S. 1056 (1990); *Pirolo v. City of Clearwater*, 711 F.2d 1006, 1010 (11th Cir. 1983) (affirming invalidation of regulations under Supremacy Clause while also affirming dismissal of § 1983 claim).

[3] *See, e.g., Medicare and Medicaid Budget Reconciliation: Hearings before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 103d Cong., 1st Sess. 453 (1993) (Rep. Waxman, describing genesis of Medicaid drug rebate program's "government-industry compact").

manufacturers and the states are protected by them for prudential standing purposes.

B. Express Preemption Is Not Required.

Maine suggests that because its use of Medicaid regulatory authority here is not expressly prohibited by the terms of the federal Medicaid statute, it is not preempted by the federal law. Opp. 9, 13. That suggestion, however, misapprehends the law of conflict preemption. It is axiomatic that federal and state laws can conflict even in the absence of a direct federal prohibition on a given state activity. Indeed, even where a federal statute and a state statute are directed to the same goals,[4] the state measure can interfere impermissibly with Congress's objectives and the means it chose to implement them in the federal law. *See, e.g., Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 379-80 (2000). Maine's threat to hold Congress's Medicaid beneficiaries hostage to efforts to subsidize state citizens who are ineligible for Medicaid necessarily interferes with Congress's goals in the federal Medicaid statute. The Act is therefore preempted.

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[4] In fact, Medicaid and the Maine Act do not serve the same objectives. Congress enacted Medicaid to provide medical services to specific categories of needy persons. The Maine Rx program is open to all residents of the state, regardless of income, age, or access to health insurance. Nor is the state's alleged "Medicaid purpose" of Maine Rx (keeping non-Medicaid individuals from becoming so poor as to qualify for Medicaid) a viable defense. The same purpose could be articulated for all state public assistance programs, yet Congress surely did not intend Medicaid regulatory authority to be employed to raise funds for them.

C. The Ruling Below Conflicts with the D.C. Circuit's Ruling in *Thompson*.

Maine obscures the simple logical conflict between the First Circuit's interpretation of the Medicaid statute here and that of the D.C. Circuit in *PhRMA v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001). The First Circuit would allow Maine to leverage its authority in administering the federal Medicaid program to secure drug price rebates for non-Medicaid patients. In *Thompson*, the D.C. Circuit refused to permit Vermont to do so, even under the auspices of the U.S. Department of Health and Human Services. As the D.C. Circuit explained, Congress in the Medicaid statute has not authorized HHS to permit states to "require pharmaceutical manufacturers to provide substantial discounts to individuals not otherwise covered by state Medicaid programs." *Id.* at 226. The two courts have thus reached opposite conclusions as to whether the Medicaid statute can be stretched to provide states with leverage to make manufacturers finance benefits for non-Medicaid populations. Particularly because this conflict presents an issue of such national currency and importance, this Court's attention is warranted.

III. The Maine Act Violates the Commerce Clause.

It is undisputed that a state may not regulate beyond its borders, even if the regulated activity has some ultimate effect in the state. Maine itself acknowledges that under the Commerce Clause it could not tax the sale of computer chips in California or the sale of oil in Texas simply because those products are later sold in Maine, Opp. 20 n.10 responding to Pet. 17 n.6. But it offers no explanation for why the same is not true of prescription drugs sold in New Jersey or other states.

Maine echoes the First Circuit's erroneous proposition that Maine Rx should be understood as an in-state regulation

with only incidental out-of-state effects. While the trigger for a Maine Rx rebate payment is an in-state pharmacy sale, the manufacturer from whom the "rebate" is demanded does not make that in-state sale. In virtually all cases, it makes *no* sale in Maine that leads to that pharmacy counter. Hence, the only transaction that Maine could be regulating when it demands a rebate from a manufacturer is the manufacturer's out-of-state wholesale sale. This constitutes hands-on regulation, tantamount to taxation, of the manufacturer's out-of-state sales.

Maine also urges that the Commerce Clause is inapposite because the Act is not a protectionist statute. That proposition misreads this Court's Commerce Clause precedents, which are not solely directed to foreclosing protectionist state legislation. The Commerce Clause also imposes basic territorial limits on state authority. This Court's opinions barring extraterritorial overreaching—such as *Baldwin v. G.A.F. Seelig*, 294 U.S. 511 (1935), *Healy v. The Beer Institute*, 491 U.S. 324 (1989), and *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986)—cannot be read as exclusively concerned about protectionism, as Maine suggests (Opp. 19).[5] Courts routinely apply the territorial doctrine of those cases. *See, e.g.*, *Dean Foods Co. v. Brancel*, 187 F.3d 609, 614-15 (7th Cir. 1999).

Even if a protectionist purpose or effect were required, the Maine Act would qualify, contrary to the state's contentions (Opp. 21-22). Maine has protected its own consumers at the expense of those outside the state. The Maine Rx program ties the amount of the rebate not to any

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[5] For example, the Court's opinion in *Healy* describes the Connecticut price affirmation statute's discriminatory aspects as a "second" Commerce Clause offense, as distinguished from its "extraterritorial reach." 491 U.S. at 340.

aspect of the in-state pharmacy sale, but to federal program rebates and prices, which in turn are based on prices around the country. That price tying will deprive consumers in the national marketplace of their competitive advantages—the very same market-distorting protectionist effects that troubled the Court in *Brown-Forman* and *Healy*. Every time a manufacturer sets a price that is the basis of the Medicaid or Federal Supply Schedule price, it will have to take into account its effect on rebates owed to Maine. The manufacturer can no longer price in the national market solely according to competitive conditions there—it must factor Maine Rx into the equation as well. This effect will be compounded at a rapid rate as other states enact "State Rx" laws, spiraling into pricing gridlock.[6]

Finally, Maine continues to assert that it is merely a market participant, Opp. 19 n.9, despite the First Circuit's decisive rejection of that argument below, App. 20. Maine is *not* a market participant—it does not buy Maine Rx drugs. On the contrary, the Act regulates manufacturers by requiring them to provide discounts to private purchasers. Maine may not leverage regulatory and market power from the Medicaid market into the Maine Rx market. *See* App. 61-64, citing *South Central Timber Dev. Inc. v. Wunnicke*, 467 U.S. 82, 96-98 (1984) (plurality op.).

CONCLUSION

For the foregoing reasons and those set out in the Petition, the Petition should be granted.

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[6] That other states may have deferred enacting copycat laws during the pendency of this suit does not diminish the urgency or national importance of the case, as Maine suggests (Opp. 25). Some 40 states have already considered price-related bills in 2001, including many modeled on Maine Rx. Such efforts are sure to be renewed in their next legislative sessions.

Respectfully submitted,

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No. 01-188

In the Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PETITIONER

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HEALTH, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

1. Whether the prior authorization provisions of the Maine Rx Program are consistent with the Medicaid statute.

2. Whether those provisions violate the Commerce Clause of the Constitution.

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States.

STATEMENT

1. a. The Medicaid program, established by Title XIX of the Social Security Act, 42 U.S.C. 1396 *et seq.*, is a cooperative federal-state program that provides federal financial assistance to States that elect to pay for medical services on behalf of certain low-income individuals. See *Harris* v. *McRae*, 448 U.S. 297, 301 (1980). The primary purpose of the Medicaid program is to "enabl[e] each State, as far as practicable under the conditions in such State, to furnish * * * medical assistance on behalf of families with dependent children

and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. 1396.

In order to participate in the Medicaid program, a State must submit a plan for medical assistance to the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration), which administers Medicaid on behalf of the Secretary of Health and Human Services (HHS). 42 U.S.C. 1396a (1994 & Supp. V 1999). The state plan specifies, *inter alia*, the categories of individuals who will receive medical assistance under the plan and the specific kinds of medical care and services that will be covered. If the plan is approved by the Secretary, the State is thereafter eligible to be reimbursed by the federal government for a specified percentage of the amounts expended as medical assistance under the state plan. 42 U.S.C. 1396b(a)(1), 1396d(b) (Supp. V 1999).

States enjoy a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. For example, the Medicaid Act does not require States to provide prescription drugs to Medicaid beneficiaries. 42 U.S.C. 1396a(a)(10)(A) (1994 & Supp. V 1999); 42 C.F.R. 440.225. The Medicaid Act does, however, specify certain individuals who are eligible to be Medicaid recipients, and it establishes a number of prerequisites for CMS approval of a State plan. 42 U.S.C. 1396a(a)(1)-(65) (1994 & Supp. V 1999). Participating States are required to make medical assistance available to certain "categorically needy" persons. 42 U.S.C. 1396a(a)(10)(A)(i) (1994 & Supp. V 1999). At a State's option, a State may additionally make medical assistance available to "medically needy" persons. 42 U.S.C.

1396a(a)(10)(C); see also *Atkins* v. *Rivera*, 477 U.S. 154, 157-158 (1986). The Medicaid Act imposes income and resource limitations on many eligibility groups described in the statute. See, *e.g.*, 42 U.S.C. 1396a(a)(10)(A)(i)(IV), (VI), (VII); see also 42 U.S.C. 1396b(f) (1994 & Supp. V 1999).

A state plan also must provide "such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan * * * as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care." 42 U.S.C. 1396a(a)(30)(A) (Supp. V 1999). As particularly relevant here, a State may subject to "prior authorization" any covered outpatient drug. 42 U.S.C. 1396r-8(d)(1)(A). Under a prior authorization program, a State requires, as a condition of coverage or payment for the drug, the prior approval of a covered outpatient drug before it is dispensed. 42 U.S.C. 1396r-8(d)(5). The Act requires that any system providing for such approval must (1) provide a response to a request for prior authorization within 24 hours of the request, and (2) provide for the dispensing of at least a 72-hour supply of the covered drug in an emergency situation. See 42 U.S.C. 1396r-8(d)(5).

b. Congress recognized that the requirements of the Social Security Act "often stand in the way of experimental programs designed to test out new ideas." S. Rep. No. 1589, 87th Cong., 2d Sess. 19 (1962). Accordingly, Congress amended the Act to authorize the Secretary to approve state demonstration projects under various titles of the Act, including Title XIX, which governs the Medicaid program. 42 U.S.C. 1315 (1994 & Supp. V 1999).

A State that wishes to conduct a demonstration project must submit an application to the Secretary. The Secretary may approve an application for a demonstration project if, "in the judgment of the Secretary," the demonstration project "is likely to assist in promoting the objectives" of the applicable programs. 42 U.S.C. 1315(a) (1994 & Supp. V 1999). If the Secretary makes such a determination for a Medicaid demonstration program, he may waive compliance with any of the requirements of 42 U.S.C. 1396a to the extent and for the period he finds necessary to enable the State to carry out the project. 42 U.S.C. 1315(a)(1). Costs of the demonstration project that would not otherwise qualify as state Medicaid expenditures may be regarded as such expenditures, subject to federal matching. 42 U.S.C. 1315(a)(2)(A) (Supp. V 1999).

2. a. This litigation presents a challenge to the prior authorization provisions of the Maine Rx Program, which was enacted in 2000 but has not yet been implemented.[1] The program was established to reduce prescription drug prices for Maine residents. Me. Rev. Stat. Ann. tit. 22 (Maine Act or Act), § 2681 (West Supp. 2001). The program is open to all Maine residents, and is designed to allow enrollees to purchase prescription drugs from participating Maine pharmacies at a discounted price. *Id.* § 2681(2)(F); Pet. App. 3.

Under the program, the State will reimburse pharmacies for such discounts out of a fund that is supported by rebate payments that the State collects from drug manufacturers. Maine Act § 2681(9); Pet. App. 3. The Act provides that a drug manufacturer that sells prescription drugs in Maine through any publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the State. Maine Act § 2681(3). The Act directs the Commissioner of the Maine Department of Human Services to negotiate the amount of the rebate required, taking into consideration the rebate calculated under the federal Medicaid rebate program administered by the Secretary of HHS (see 42 U.S.C. 1396r-8(a)-(c)(1994 & Supp. V 1999)) and using his best efforts to obtain an initial rebate amount equal to or greater than that amount. Maine Act § 2681(4).[2]

The Maine Act provides for the public disclosure of the names of manufacturers that do not enter into rebate agreements with the State. Maine Act § 2681(7). And as particularly relevant here, the Act directs the Maine Department of Human Services to "impose prior authorization requirements in the Medicaid program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers." *Ibid.*

b. Petitioner Pharmaceutical Research & Manufacturers of America brought this action in the United States District Court for the District of Maine to challenge, *inter alia*, the prior authorization provisions of the Maine Rx Program. The district court entered a

[1] Other aspects of the Maine Rx Program have been challenged but those challenges are not before this Court. See Pet. App. 5 n.2.

[2] Under the federal rebate program, if the drug in question is either a single source drug or an innovator multiple source drug, the rebate due on each unit paid for under the State plan is generally the difference between the "average manufacturer price" and the manufacturer's "best price," defined as the lowest price available from the manufacturer to any private purchaser or governmental entity within the United States. 42 U.S.C. 1396r-8(c)(1)(A), (B), and (C) and (c)(2). For other drugs, the rebate is 11%. 42 U.S.C. 1396r-8(c)(3). Rebates are calculated and paid on a quarterly basis. 42 U.S.C. 1396r-8(b)(1)-(3), 1396r-8(k)(8).

preliminary injunction barring the enforcement of the prior authorization requirement against any drug manufacturer that does not enter into a rebate agreement with the State. Pet. App. 57-72.

The district court first held that invocation of a prior authorization provision in this manner is inconsistent with the objectives of the Medicaid statute. Pet. App. 66-71. The court explained that the purposes of the Medicaid statute are to provide medical services, including prescription drugs, to individuals who are eligible for Medicaid, and observed that Congress thus has required that a state plan ensure that care and services will be provided "in a manner consistent with the best interests" of Medicaid recipients. *Id.* at 67-68 (quoting 42 U.S.C. 1396a(a)(19)) (emphasis omitted). In the court's view, the prior authorization provisions could not be enforced because Maine could not identify any Medicaid purpose that those provisions would serve. *Ibid.*

The court also concluded that the prior authorization provisions violate the Commerce Clause. Pet. App. 61-66. The court first rejected the argument that Maine was acting as a market participant in enacting and administering the Maine Rx Program, noting that Maine is attempting to influence the terms of transactions to which it is not a party. *Id.* at 62-64. The court then opined that the "practical effect of what Maine has done here is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine." *Id.* at 66. The court held that this consequence renders the rebate program an unconstitutional effort to legislate extraterritorially. *Ibid.*

3. The court of appeals reversed and vacated the preliminary injunction. Pet. App. 1-53. After determining that petitioner had standing to sue (*id.* at 6-8), the court rejected its arguments on the merits. The court perceived "no conflict between the Maine Act and Medicaid's structure and purpose." *Id.* at 11. The court observed that the Medicaid statute authorizes the States to impose prior authorization requirements, as long as a response to a request for authorization to dispense a drug is given within 24 hours and a 72-hour emergency supply is dispensed. *Ibid.* (citing 42 U.S.C. 1396r-8(d)(5)(A) and (B)). In the court's view, the language of the Maine Act directing that prior authorization requirements be imposed "as permitted by law" limits the Maine Act's application to situations in which prior authorization is permitted by Medicaid. *Ibid.* (quoting Maine Act § 2681(7)). The court expressed concern that if prior approval is required for drugs produced by manufacturers that do not enter into rebate agreements, "first-choice drugs will not be readily approved where second-choice inferior alternatives exist." *Id.* at 17. But the court found insufficient evidence to invalidate the prior authorization provisions on that basis in the context of petitioner's facial challenge to the Maine Rx Program. *Id.* at 14-17.

The court also rejected petitioner's argument that it would be necessary to invalidate Maine's prior authorization provisions if they advanced no Medicaid purpose, concluding that the absence of a Medicaid purpose "does not necessarily mean that the prior authorization scheme *conflicts* with the objectives of the Medicaid program." Pet. App. 12-13. In addition, however, the court concluded that the Maine Rx Program does serve Medicaid purposes. The court reasoned that the Maine Rx Program "furthers Medicaid's aim of providing medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical

services,' 42 U.S.C. § 1396, even if the individuals covered by the Maine Rx Program are not poor enough to qualify for Medicaid." *Id.* at 13. The court also stated that "there is some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures." *Ibid.* The court explained that, "[w]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible." *Ibid.*

Finally, the court rejected petitioner's contention that the Maine Act is unconstitutional under the Commerce Clause. Although the court agreed with the district court that Maine was not acting as a market participant in enacting the Maine Rx Program, see Pet. App. 20, it concluded that the prior authorization provisions do not constitute extraterritorial regulation. The court observed that, unlike the state statutes invalidated by this Court under the Commerce Clause, "the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect." *Id.* at 22. The court explained that "Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price," and held that "[s]imply because the manufacturers' profits might be negatively affected by the Maine Act * * * does not necessarily mean that the Maine Act is regulating those profits." *Id.* at 22-23.[3]

[3] Judge Keeton filed a concurring opinion that stressed the difficulty of prevailing on a facial challenge. Pet. App. 31-53. No action was taken on petitioner's petition for rehearing *en banc* because all but one of the active judges on the court of appeals were recused. See *id.* at 54-55. Chief Judge Torruella voted to rehear the case *en banc*. *Id.* at 55.

DISCUSSION

Review of the court of appeals' decision is not warranted, especially at this interlocutory stage of the case. The court of appeals vacated the preliminary injunction entered by the district court in the context of petitioner's facial challenge to the Maine Rx Program in advance of its implementation. The courts below may consider additional factual and legal arguments in the course of further proceedings leading up to entry of a final judgment. Furthermore, the court of appeals' decision represents the first appellate decision to address whether the Medicaid Act bars a State from subjecting drugs to prior authorization under its Medicaid program in order to reduce drug prices for *non*-Medicaid populations.

Nor is this Court's review necessary to establish a rule that state programs necessarily conflict with the Medicaid statute whenever they operate in part to benefit a non-Medicaid population. There could be situations in which a State might seek to implement a program that, unlike the Maine Rx Program, is tailored to benefit individuals who are financially needy, but not Medicaid-eligible, in order to decrease the likelihood that they would *become* Medicaid-eligible. Indeed, other States have sought approval for similar programs under the Secretary's authority to approve demonstration projects calculated to "promot[e] the objectives" of the Medicaid program, 42 U.S.C. 1315(a) (1994 & Supp. V 1999), and the Secretary of HHS, who is charged with administering the Medicaid program, is in the process of considering those requests. The Secretary should be

permitted to use the existing administrative process to develop principled distinctions between permissible and impermissible state programs before this Court addresses those questions.[4] If a circuit conflict should develop after the Secretary has reviewed those applications and developed criteria, or if issues should then persist or emerge that warrant this Court's review, the Court would have occasion to grant review at that time.

Petitioner's constitutional challenge likewise does not warrant review. The court of appeals was correct to reject the argument that the Maine Rx Program regulates extraterritorially, and that ruling does not conflict with the ruling of any other court of appeals.

1. a. The court of appeals "perceive[d] no conflict between the Maine Act and Medicaid's structure and purpose" because, even assuming that the Maine Act has no "Medicaid purpose," the Maine Act, in the court's view, does not "*conflict[]* with the objectives of the Medicaid program." Pet. App. 11, 13. That perception may well have been incorrect, but especially given the posture of the case, it does not warrant review by this Court.

Under the Maine Act, the State "shall impose [the] prior authorization requirements in the Medicaid program" on any drug manufacturer that does not enter

[4] The Secretary is exploring several avenues for making prescription drugs more available to low-income individuals, including seniors, who are not Medicaid eligible. For example, the Secretary recently announced a new initiative, known as "Pharmacy Plus," that will make it easier financially and administratively for States to obtain the Secretary's approval for demonstration projects under Section 1315 to expand prescription drug benefits to low-income individuals. See also pp. 13, 15, *infra* (discussing, inter alia, HHS approval of Illinois' prescription drug demonstration project under Section 1315).

into a rebate agreement with the State for drugs dispensed to *non*-Medicaid patients. Maine Act § 2681(7). Thus, the State program on its face is designed to serve the State's *non-Medicaid* population by imposing a burden on the ability of *Medicaid* recipients to receive an otherwise covered outpatient drug that is prescribed by a physician. See Pet. App. 17.

While States participating under Medicaid must ensure that covered services will be provided in a manner consistent with "the best interests of [Medicaid] recipients," 42 U.S.C. 1396a(a)(19), that provision of course must be read in light of other provisions of the Medicaid Act that, *inter alia*, require a State to provide such procedures as may be necessary "to safeguard against unnecessary utilization" of services and to assure that payments are consistent with "efficiency, economy, and quality of care." 42 U.S.C. 1396a(a)(30)(A) (Supp. V 1999). Congress therefore has authorized States under certain conditions to impose prior authorization requirements on otherwise covered outpatient drugs. 42 U.S.C. 1396r-8(a) (1994 & Supp. V 1999); 42 U.S.C. 1396r-8(d)(5). Congress enacted those provisions so that States "would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." H.R. Rep. No. 881, 101st Cong., 2d Sess. 98 (1990). Congress assuredly did not intend that a State would use a requirement of prior authorization for the prescription of drugs for Medicaid beneficiaries in a manner that would burden the ability of Medicaid recipients to receive covered drugs without serving *some* purpose related to Medicaid.

It is possible that a state prior authorization requirement might advance Medicaid-related goals. For instance, as a result of the eligibility restrictions under Medicaid, many lower-income individuals who find it difficult to pay for needed medical care are nevertheless not Medicaid-eligible. As of 1998, only 40 percent of those persons with incomes below the federal poverty level were covered by Medicaid. See Staff of House Comm. on Ways and Means, 106th Cong., 2d Sess., *2000 Green Book* 902 (Comm. Print 2000). A prescription drug discount, made possible by encouraging manufacturers to give rebates to the State, may significantly decrease the chance that such individuals will become Medicaid-eligible. Thus, had Maine tailored its Rx Program to benefit such low-income individuals, it might have been able to demonstrate that the prior authorization requirement would sufficiently advance a Medicaid purpose to be approved by the Secretary of HHS pursuant to his various authorities under the Medicaid statute.

The court of appeals suggested that the Maine Rx Program could be sustained because there was "some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures." Pet. App. 13. The Maine Rx Program, however, is open to all Maine residents, regardless of financial need, *id.* at 3, and the Maine Act's statement of purposes reveals no Medicaid objective. See 1999 Me. Laws ch. 786, § A-5(3) (the law was enacted "to make prescription drugs more affordable for Maine residents, thereby increasing the overall health of our families, benefitting employers and employees and the fiscal strength of our society, promoting healthy communities and increasing the public health and welfare").

Indeed, the Maine Rx Program stands in contrast to the design of a demonstration project that Maine itself has been conducting with the approval of the Secretary of HHS under 42 U.S.C. 1315. See Me. Rev. Stat. Ann. tit. 22, § 258 (West Supp. 2001). Unlike the Maine Rx Program, the demonstration project (known as the Healthy Maine Prescription Program) is specifically tailored to provide prescription drug discounts to Maine residents with household incomes of up to 300% of the federal poverty level. Individuals eligible for benefits under this demonstration project would have little incentive to enroll in the Maine Rx Program because the demonstration project appears to offer greater benefits. Thus, as a practical matter, the Maine Rx Program essentially targets persons whose income is in excess of 300% of the federal poverty level. Based on the record to date and in the absence of actual experience under the Maine Rx Program, no Medicaid purpose appears to be served by a state program focusing on that population.[5]

b. Petitioner urges (Pet. 22) this Court to grant certiorari because other States are considering passing drug rebate programs similar to the Maine Rx Program. We do not yet know whether a significant number of States will pass such legislation, however, and the decision below is the first appellate decision to address the validity of such a law under the Medicaid Act. Contrary to petitioner's contention (Pet. 11-13), the decision below does not conflict with the D.C. Circuit's decision in *PhRMA* v. *Thompson*, 251 F.3d 219

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[5] Maine's demonstration project has been upheld against a challenge by petitioners. See *Pharmaceutical Research & Mfrs. of America* (*PhRMA*) v. *Thompson*, 191 F. Supp. 2d 48 (D.D.C. 2002), appeal pending, No. 02-5110 (D.C. Cir.).

(2001), which addressed a different, although related, set of issues under a different statutory provision of the Medicaid Act. In that case, petitioner successfully challenged a Vermont demonstration project under which the State required drug manufacturers to pay rebates for drugs purchased by certain individuals who were otherwise not covered by the State's Medicaid program. The court's analysis turned on the meaning of a Medicaid provision stating that manufacturers owe rebates only for drugs "for which payment was made under the State plan." See *id.* at 226 (quoting 42 U.S.C. 1396r-8(b)(1)(A)). Although Vermont paid, on behalf of the beneficiaries of the demonstration project, a portion of the price of prescription drugs, the court determined that those payments were not "payments" within the meaning of the relevant Medicaid provision because they were subsequently reimbursed through the manufacturer rebates and thus involved no expenditure of government funds. See *id.* at 224-226.

The Vermont project at issue in *Thompson* did not rely on prior authorization requirements to encourage manufacturer rebates, and the court did not consider the question whether such requirements would be consistent with the Medicaid statute's structure and purpose. Review by this Court is therefore not necessary to resolve a conflict in the circuits.

Nor is this Court's review necessary to determine, as petitioner urges (Pet. 21-23), whether, as a general rule, States may impose requirements under Medicaid in order to serve non-Medicaid populations. As discussed above, if such a requirement were suitably tailored to serve Medicaid-related program goals, it might well be consistent with the Medicaid statute. The State of Maine, however, adopted its program unilaterally, with no involvement or approval by the Secretary, and its

program is unusual in that it uses the State's Medicaid prior-approval authority to achieve ends unrelated to the Medicaid program itself.

The Secretary of HHS, who is charged with administering the Medicaid program, is evaluating requests by other States that seek to reduce prescription drug costs by requesting the Secretary to exercise his authority to authorize demonstration projects under 42 U.S.C. 1315 and to approve state plan amendments under 42 U.S.C. 1396a(b). For instance, HHS has informed this Office that on January 28, 2002, CMS approved under its Section 1315 demonstration project authority a proposal by the State of Illinois to provide comprehensive pharmacy benefits, with primary care coordination, to senior citizens with incomes at or below 200% of the federal poverty level. And, as described above, the Secretary also has approved a demonstration project for the State of Maine. Particularly in these circumstances and in the absence of any conflict in the circuits on the question presented, this Court's review would be premature.

c. The court of appeals' rejection of petitioner's facial challenge to the Maine Rx Program under the Commerce Clause likewise does not warrant this Court's review. The decision of the court of appeals is correct on that issue, and it does not conflict with the ruling of another court of appeals.

It is well established that the Commerce Clause precludes extraterritorial state regulation, that is, state regulation of commerce that occurs outside the State's borders. See, *e.g.*, *Healy* v. *Beer Institute*, 491 U.S. 324, 336 (1989). By prohibiting extraterritorial state regulation, the Commerce Clause protects "against inconsistent legislation arising from the projection of one

state regulatory regime into the jurisdiction of another State." *Id.* at 337.

A state regulation may be impermissibly extraterritorial even if, in a narrow sense, it addresses conduct that occurs within the State. The critical inquiry is whether "the practical effect of the regulation is to control conduct beyond the boundaries of the State." 491 U.S. at 336.

Thus, in *Healy*, this Court invalidated a Connecticut statute that required beer distributors to file a statement that their Connecticut prices did not exceed the price charged by the distributor in any neighboring State. 491 U.S. at 328-329 & n.5. Although the state statute appeared to be aimed at in-state conduct, the court held it unconstitutional because it had the practical effect of precluding the distributors from reacting to different market conditions that might exist in neighboring States. *Id.* at 338. See *Brown-Forman Distillers Corp.* v. *New York State Liquor Auth.*, 476 U.S. 573, 583 (1986) (invalidating a similar state statute).

Similarly, in *Edgar* v. *MITE Corp.*, 457 U.S. 624, 642-643 (1982) (plurality opinion), the Court invalidated an Illinois statute that purported to give Illinois authority to regulate interstate tender offers if the target company had certain specified connections to the State. In striking down the statute, the Court noted that it would give Illinois the power to block a corporate takeover even if takeover would not affect a single Illinois shareholder. See *id.* at 642. The plurality concluded that the Illinois law "directly regulates transactions which take place across state lines, even if wholly outside the State of Illinois," *id.* at 641, and observed that if Illinois were free to enact such legislation, other States similarly were so empowered, "and interstate commerce in securities transactions generated by tender offers would be thoroughly stifled," *id.* at 642. See also *BMW of North America, Inc.* v. *Gore*, 517 U.S. 559, 572 (1996) ("We think it follows from these principles of state sovereignty and comity that a State may not impose economic sanctions on violators of its laws with the intent of changing the tortfeasors' lawful conduct in other States."); *Dean Foods Co.* v. *Brancel*, 187 F.3d 609, 619 (7th Cir. 1999) (Wisconsin could not prohibit volume discounts to an Illinois milk processor's purchase of milk in Illinois, even though the milk was originally produced by Wisconsin dairies).

The Maine Rx Program does not contravene the foregoing principles. The rebates that participating drug manufacturers would pay to Maine are triggered by the sale, in Maine, of the manufacturers' products. Although petitioner notes that most manufacturers sell their drugs to out-of-state intermediaries before the products reach Maine, see Pet. 15, the Maine Rx Program does not regulate the terms of those out-of-state transactions. Indeed, petitioner's broad reasoning would condemn a wide variety of permissible state regulations that may affect the conduct of out-of-state manufacturers, such as those imposing liability on out-of-state drug manufacturers for the in-state sale of defective or unreasonably dangerous drugs or requiring that all automobiles sold in-state meet state emissions standards.[6]

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[6] For similar reasons, if the Maine Rx Program were regarded as imposing a tax on out-of-state drug manufacturers, the Program would satisfy the requirement that such a tax be applied "to an activity with a substantial nexus with the taxing State." *Complete Auto Transit, Inc.* v. *Brady*, 430 U.S. 274, 279 (1977). The court of appeals did not address that issue because petitioner did not present it to the district court. Pet. App. 27 n.11.

Nor does the Maine Rx Program directly link the amount of the rebates to the rebate amount paid under the Medicaid program pursuant to a national rebate agreement entered into by the Secretary of HHS pursuant to 42 U.S.C. 1396r-8. To be sure, the Maine statute directs the state commissioner, in "negotiat-[ing]" the amount of the rebate, to "take into consideration" the rebate calculated under the Medicaid program, and to use his "best efforts" to obtain a rebate equal to or greater than that amount for non-Medicaid beneficiaries. See Maine Act § 2681(4). As the court of appeals concluded, however, those provisions do not purport to regulate or control the amount of rebates paid out-of-state. See Pet. App. 23; see also W. Phelps, *Maine's Prescription Drug Plan: A Look into the Controversy*, 65 Alb. L. Rev. 243, 266 (2001) ("The Maine statute does not link Maine's prices to any other state and thus does not interfere with competition in the marketplace between manufacturers."). Accordingly, the court of appeals' ruling that the Maine Rx Program comports with the Commerce Clause does not warrant further review by this Court.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

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SUPPLEMENTAL BRIEF OF PETITIONER

Pursuant to Rule 15.8, Petitioner Pharmaceutical Research and Manufacturers of America ("PhRMA") files this supplemental brief in response to the Brief of the United States as *Amicus Curiae*, which was filed on May 30, 2002 pursuant to this Court's order of October 9, 2001.

I. THE SOLICITOR GENERAL AGREES THAT THE FIRST CIRCUIT'S DECISION ON THE SUPREMACY CLAUSE ISSUE WAS IN ERROR.

The Solicitor General agrees with Petitioner that the Maine Rx program's use of Medicaid prior authorization to benefit non-Medicaid patients conflicts with the federal Medicaid statute, and that the court of appeals erred on the Supremacy Clause issue (first question presented, Pet. at i).

The Solicitor General notes without qualification that prior authorization "burden[s] the ability of Medicaid recipients to receive covered drugs." U.S. Br. at 11.[1] Because prior authorization imposes that burden on Congress's intended beneficiaries, the Solicitor General also concludes that its use must further at least *some* Medicaid purpose. *Id.* In the view of the United States, Maine cannot use Medicaid prior authorization for any purpose it desires; the First Circuit, however, doubted that any such constraint exists, Pet. App. at 12. Most important, the Solicitor General states clearly that "no Medicaid purpose appears to be served" by the Maine Rx program. U.S. Br. at 13. In sum, the only conclusion to be drawn from the Solicitor General's brief is that the Maine Rx program conflicts on its face with the Medicaid statute – a straightforward rejection of the First Circuit's holding that no such conflict exists, Pet. App. at 13-14.

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[1] The First Circuit, in contrast, held that that burden is not evident on its face, and must be proven by evidence of harm to Medicaid recipients. Pet. App. at 16-17.

II. THE SOLICITOR GENERAL'S REASONS FOR RECOMMENDING AGAINST REVIEW DO NOT WITHSTAND SCRUTINY.

If this Court declines review, it is the First Circuit's flawed reading of the federal Medicaid statute, and not the Solicitor General's contrary interpretation, that will be law. Curiously, the Solicitor General nevertheless recommends against granting certiorari. But none of the reasons offered for denying review – that the decision below is interlocutory, that no other appellate court has yet addressed the statutory issue, or that the U.S. Department of Health and Human Services should be left to deal with the states on issues of expanded prescription drug coverage – justifies allowing the decision below to stand unreviewed.

Although this case was decided on a motion for a preliminary injunction, no further development of the record would contribute to or alter the relevant legal analysis. The Solicitor General has already shown how the Maine Rx program facially conflicts with the federal Medicaid statute, because it burdens Medicaid prescription drug benefits for ends unrelated to those of the Medicaid statute. U.S. Br. at 11, 13, 15. No additional factual development is required to complete that legal analysis, and none is suggested by the government.

For similar reasons, the Court should not await review by other courts of appeals of other "State Rx" programs to come.[2] As noted in the Petition, states around the country are

[2] The Solicitor General is mistaken that the First Circuit's decision is "the first appellate decision to address the validity of such a law." U.S. Br. at 9, 13. The D.C. Circuit has also considered (and rejected) a state effort to leverage Medicaid authority to benefit non-Medicaid populations. Specifically, it rejected a state's effort to "require pharmaceutical manufacturers to provide substantial discounts to individuals not otherwise covered by state Medicaid programs" in *PhRMA v. Thompson*, 251 F.3d 219, 226 (D.C. Cir. 2001). Notwithstanding the different statutory texts at issue, the D.C. Circuit decision conflicts with the First Circuit's holding that such leveraging is compatible with the Medicaid statute. Pet. at 11-13.

poised to act on the basis of this Court's guidance.[3] The conflict issue – whether states may leverage federal Medicaid powers for non-Medicaid purposes – is clear now, and consideration by other courts of appeal will not further illuminate it. With no prospect of legal clarification, all that will be furthered by delaying this Court's intervention is litigation and administrative confusion as programs are tied up in court.

Finally, the Court should not be dissuaded from review by the Solicitor General's plea to leave to HHS the job of policing states to ensure that their prescription drug programs are consistent with the Medicaid statute. The First Circuit's decision is a legal green light for other states to copy Maine's program, and, other than chastising Maine in the Solicitor General's brief, neither HHS nor any other executive authority has taken action to stop the Maine Rx program or prevent other states from adopting similar programs. Indeed, HHS has already approved[4] state programs that have the very features – such as wide availability to persons many of whom are in no danger of becoming Medicaid patients – that the

[3] "State Rx" copycat proposals have proliferated in state legislatures, *see* Pet. at 21-23, and the flurry of Medicaid waiver applications mentioned in the Solicitor General's brief further evidences that states are bent on pursuing all options available to them. Unless this Court intervenes, the Maine Rx program – which the United States recognizes will burden Medicaid yet serve no Medicaid purpose – will stand as the court-endorsed model for their efforts.

[4] In addition to the demonstration programs discussed in the Solicitor General's brief, U.S. Br. at 3-4, 13, the Secretary of HHS can also consider requests from states to amend directly the state plans under which they administer Medicaid benefits. Maine never pursued, and HHS has not required, any such amendment for the Maine Rx program – omissions that cast further doubt on HHS's putative ability to rein in state programs.

Solicitor General now condemns as incompatible with Medicaid.[5]

The Solicitor General rightly condemns Maine for "unilaterally" using Medicaid authority in Maine Rx "to achieve ends unrelated to the Medicaid program itself." U.S. Br. at 14-15. But, if states are free to enact Maine Rx-style programs, they will have no reason to seek federal approval for the more tailored Medicaid waiver programs and state plan amendments that the Solicitor General endorses in his brief. *See id.* at 13, 15. A state will have little incentive to create and negotiate federal approval for a more limited program if it believes it can unilaterally obtain comparable benefits for all its citizens at no cost to the state under a program like Maine Rx.

III. THE SOLICITOR GENERAL MISAPPREHENDS THE COMMERCE CLAUSE VIOLATIONS INHERENT IN THE MAINE RX PROGRAM.

As the Solicitor General notes, this Court's Commerce Clause precedents prohibit extraterritorial state regulation "even if, in a narrow sense, it addresses conduct that occurs within the State. The critical inquiry is whether 'the practical effect of the regulation is to control conduct beyond the boundaries of the State.'" *Id.* at 16 (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989)). Yet the Solicitor General fails to appreciate that the Maine Rx program – in which a state demands payment from out of state manufacturers based on third parties' in-state sales of their products – fails this very inquiry.

The Solicitor General falls victim to the same fallacy that led the First Circuit's Commerce Clause analysis astray – the

[5] On January 28, 2002, for example, the Secretary approved a Michigan state plan amendment under which the state will use the threat of Medicaid prior authorization to obtain, *inter alia*, manufacturer rebates for residents enrolled in the state's non-Medicaid health programs.

notion that the Maine Rx rebate requirement regulates "the sale, in Maine, of the manufacturers' products." U.S. Br. at 17. But, as the Petition demonstrates, in-state sales are not what are regulated; they are only the trigger for Maine's regulation of sales transactions between manufacturers and wholesalers in other states. Pet. at 14-17. The rebate required by Maine has the same effect as a duty imposed at the state's border: it reduces the price received by the manufacturer outside Maine on the units of its drugs that are eventually sold in Maine. While the government suggests that "the Maine Rx Program does not regulate the terms of those out-of-state transactions," U.S. Br. at 17, it has no adequate answer to the question "what *else* could a demand for payment be regulating, when it is directed to entities that engage in no other transactions involving the drugs that trigger the demand?"

The Solicitor General warns that invalidating Maine's rebate demands as extraterritorial would also condemn state tort and product safety laws as Commerce Clause violations. The analogy is inapt. Maine is demanding money from out-of-state manufacturers based solely on the fact that their products reach the state. This direct regulation of out-of-state manufacturers' revenue is a far cry from health and safety regulation of the products themselves that only incidentally affect companies' costs of doing business. The difference is between direct regulation of out-of-state commerce on the one hand, and in-state regulation with incidental out-of-state effects on the other. Maine Rx rebates are in the former category, and thus violate the Commerce Clause.

Finally, the Solicitor General repeats the error of the First Circuit in supposing that Maine has not engaged in impermissible price tying because the statute directs the commissioner to use his best efforts to "negotiate" rebates as large as those charged around the country. As explained in PhRMA's prior filings, the Maine Rx program leaves nothing to "negotiate." *See* Pet. at 19; Reply at 2-3. Clever drafting

cannot obscure the Maine Rx program's mandatory nature, or excuse its use of price tying in violation of the Commerce Clause. The Commerce Clause boundaries of states' legislative authority are clearly at issue in the petition, and warrant this Court's clarification.

CONCLUSION

For the foregoing reasons and those set forth in Petitioner's previous filings, the petition for certiorari should be granted.

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No. 01-188

IN THE
SUPREME COURT OF THE UNITED STATES

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF THE STATE OF MAINE,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF AMICUS CURIAE OF THE CHAMBER OF COMMERCE OF THE UNITED STATES IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Can a state, consistent with the Supremacy Clause, deny participation in a federally funded program as a means of coercing participation in an unrelated state program?

2. Can a state, consistent with the Commerce Clause, regulate the prices charged in sales transactions taking place outside its borders, by requiring an out-of-state manufacturer to pay a rebate to the state whenever its products are re-sold by a retailer in the state?

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CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States is a not for profit corporation that has neither a parent nor stockholders.

INTERESTS OF AMICUS CURIAE

The Chamber of Commerce of the United States of America (the 'Chamber") is the world's largest federation of businesses, representing an underlying membership of nearly 3,000,000 businesses and organizations, with direct members of every size, in every sector of the economy, and every region of the country. While most of the country's largest companies belong to the Chamber, the vast majority of its members are small businesses with fewer than 100 employees. Chamber members transact business in all or nearly all of the United States, as well as in a large number of countries around the world. An important function of the Chamber is to represent the interests of its members in important matters before the courts, Congress, and the Executive Branch. To that end, the Chamber has filed amicus curiae briefs in numerous cases that have raised issues of vital concern to the nation's business community.

Many of the Chamber's members engage in multi-state operations, and the question whether one state can regulate transactions or other conduct taking place entirely in another state is therefore of direct interest and concern to Chamber members. Equally important to Chamber members is any sanctioning of a state's use of its power over federal funding to force private parties to make financial or other contributions to unrelated state programs. The Maine statute at issue here implicates both of these concerns. The Chamber files this brief with the consent of all parties. [1]

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[1] No counsel for any party authored this brief in whole or in part. No person or entity other than the Chamber, its (...continued)

SUMMARY OF ARGUMENT

The salient facts presented by this petition are straightforward and uncontroverted: A manufacturer ("Manufacturer") sells and ships its product to a wholesaler ("Wholesaler"). The sale is made entirely outside Maine. Wholesaler then sells and ships the products to retailers in a number of states, including Maine, and the retailers in turn sells the products to consumers. The price for which Manufacturer sells its products to Wholesaler is the foundation of the price for which Wholesaler sells the products to retailers. That price, in turn, is the foundation of the price for which retailers sell the products to consumers.

The prices that Manufacturer is charging to Wholesaler result in retail prices that Maine deems too high. Maine, therefore, enacted legislation that: (1) forces Manufacturer to pay "rebates" to the State to subsidize discounts on the retail prices consumers pay, and (2) curtails Manufacturer's participation in unrelated federal programs if it refuses to make such payments. The legislation is thus the functional equivalent of a command to Manufacturer to reduce its prices to Wholesaler. As the district court in this case observed, "whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced [by the mandatory rebate] when the drug comes to Maine." (App. 66).

The district court correctly held that, under the Supremacy Clause, a state cannot use the threat of limiting a private party's participation in a federal program to coerce its participation in an unrelated state program; and that, under

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members, or its counsel made a monetary contribution to the preparation or submission of this brief.

the Commerce Clause, a state lacks power to regulate the terms of a transaction that takes place entirely outside its borders. The appellate court's reversal of those holdings conflicts with precedents from other circuits, and would permit states both to hijack federal programs in order to serve their own parochial ends and to assert regulatory powers far beyond their borders.

REASONS FOR GRANTING THE WRIT

I. THE FIRST CIRCUIT DECISION WOULD ALLOW STATES TO HIJACK FEDERAL PROGRAMS FOR UNRELATED PURPOSES, AND CONFLICTS WITH A DECISION OF THE D.C. CIRCUIT.

The Medicaid program provides prescription drugs and other medical services to those with medical needs who meet the statute's eligibility requirements. 42 U.S.C. § 1396 (2001). These eligibility requirements are spelled out in great detail in the federal statute, *see* 42 U.S.C. § 1396a(a)(10) (2001), and are met by approximately 170,000 Maine residents. (JA 89). The federal government pays two-thirds of Maine Medicaid expenses. *See* 65 Fed. Reg. 8979-80, 69560-61 (2001).

The Maine "Act to Establish Fairer Pricing for Prescription Drugs," 2000 Me. Legis. Ch. 786 (the "Maine Rx Act"), purports to require drug companies to enter into "rebate agreements" in order to reduce the price of prescription drugs purchased by at least 325,000 Maine citizens who do not qualify for the Medicaid program, and potentially all Maine residents. Me. Rev. Stat. Ann. tit. 22 § 2681 (West 2000); JA 144; App. 3. These rebate agreements are required for any drug company that participates in any publicly supported pharmaceutical assistance program, such as the federal Medicaid program. Me. Rev. Stat. Ann. tit. 22

§ 2681(3). These rebates are collected by the state and provided to pharmacists in order to reimburse them for price discounts funded entirely by the rebates. *Id.* at § 2681(9); *see also* App. 3.

The Maine Rx Act provides that the State will restrict patient access under the federal Medicaid program to the drugs of any manufacturer that fails to enter into a rebate agreement. Me. Rev. Stat. Ann. tit. 22 § 2681(7). The Act accomplishes this goal by requiring "prior authorization" by the state Medicaid administrator for Medicaid prescriptions of drugs made by manufacturers that have refused to enter into rebate agreements. *Id.*; *see also* App. 4. As the district court found (App. 71) and the Court of Appeals did not dispute (App. 15), prior authorization often reduces access to drugs subject to this requirement, either because doctors will simply substitute other drugs not subject to prior authorization, or the state will not provide the requisite authorization. [2]

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[2] The Maine Rx Act also contains additional enforcement mechanisms. The Act provides that non-cooperating drug companies may be charged with "profiteering," which is defined to include "unconscionable" pricing and which exposes the company to a panoply of sanctions: treble damages, punitive damages if the violation was determined to have been willful or repeated, civil penalties of up to $100,000 per violation, and injunctive relief. Me. Rev. Stat. Ann. tit. 22 § 2697(1)(2)(3)(4) (West 2000). A violation of the anti-profiteering prohibition is automatically also a violation of the Maine Unfair Trade Practices Act, *id* at. § 2697(5), which itself provides for civil penalties of up to $10,000 per violation, private actions for actual damages, and injunctive relief. Me. Rev. Stat. Ann. tit. 5, §§ 209, 213 (West 2000). Respondent did not appeal the district court's
(...continued)

A. *Conflict with federal law*. There is no question that Congress intended to permit states, under appropriate circumstances, to impose a "prior authorization" requirement on prescription drugs reimbursed under the federal Medicaid program *in order to benefit that program or its beneficiaries,* for example, to ensure cost-effective Medicaid operations by preventing the over prescription to Medicaid recipients of popular but expensive drugs. *See* 42 U.S.C. § 1396r-8(d)(1). But here the state is doing something radically different. It is purporting to use its power to impose a Medicaid "prior authorization" requirement in order to punish a drug company's refusal to participate in the unrelated state "rebate" program for hundreds of thousands of citizens who do not qualify for the Medicaid program, Me. Rev. Stat. Ann. tit. 22, § 2681(7); JA 144.

That action, by its very nature, interferes with the purposes of the Medicaid program. Prescription drugs that had previously been freely available to Medicaid patients suddenly will not be, for reasons having nothing to do with the interests of the Medicaid program or Medicaid beneficiaries. *See* App. 71 ("The State makes no argument that the new condition of prior approval serves any purpose of the Medicaid program."). Yet the Medicaid statute explicitly provides that a state cannot design its Medicaid program to serve other interests, but must instead "provide such safeguards as may be necessary to assure that…care and services will be provided, in a manner consistent with…the best interest of *the recipients.*" 42 U.S.C. § 1396a(a)(19) (emphasis added).

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ruling enjoining enforcement of these provisions. *See* App. 5 n.2.

This state conduct runs afoul of the Supremacy Clause, U.S. Const. art. VI, § 2. A state may not take action that imposes an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373 (2000)(citation omitted). Maine inevitably does that when it burdens access to drugs under the Medicaid program to serve non-Medicaid ends. Indeed, as the district court noted, the Maine Rx Act flouts the principle of federal supremacy not merely because it "might conflict with the objectives of a federal law," but because it "has actually taken the federal Medicaid program and altered it to serve Maine's local purposes." (App. 68); *see also id.* at 69 n.12 ("the Medicaid program [has been] hijacked to provide leverage for other purposes.").

The First Circuit erred in holding that proof of a conflict would have to await evidence that the health of a Medicaid patient had actually been harmed by the denial of necessary drugs. (App. 16). Respondent concedes that the state "will not authorize payment for [a] first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant…." (App. 15). So long as the Maine statute serves its intended function of causing a doctor to prescribe for a Medicaid patient a drug different than the drug he would otherwise have preferred—an effect the First Circuit did not deny—the Medicaid program has been negatively impacted for purposes unrelated to that program.

Maine was not obligated to participate in the Medicaid program, but having chosen to do so, must comply with the requirements of the federal Medicaid law. *See Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 502 (1990); *Alexander v. Choate,* 469 U.S. 287, 289 n.1 (1985). Maine fails to meet that obligation when it subverts the Medicaid

program and the interest of Medicaid beneficiaries in order to serve other purposes.

B. *Conflict with D.C. Circuit*. Maine seeks to impose through its administration of the Medicaid program the very regime that the D.C. Circuit recently held the Medicaid statute does not permit—one in which "pharmaceutical manufacturers [must] provide substantial discounts to individuals not otherwise covered by state Medicaid programs." *PhRMA v. Thompson*, 251 F.3d 219, 226 (D.C. Cir. 2001). That court struck down as beyond Medicaid's statutory authority a federal waiver allowing Vermont to require rebates from manufacturers in order to reduce the cost of pharmaceutical drugs to persons not meeting Medicaid's eligibility requirements. If, as the D.C. Circuit held, such a regime is beyond that permitted by Medicaid's express terms, then *a fortiori* it is impermissible for a state to restrict benefits otherwise available to Medicaid participants in order to achieve precisely the same result. The circuit decisions are in conflict and merit this Court's review.

The implications of Maine's conduct go well beyond the specifics of this case. Other states are now considering similar legislation. *See* Pet. for a Writ of Cert. at 21-23. Furthermore, as the district court noted, Maine could just as easily have used its authority over Medicaid authorization to coerce drug companies to make contributions to highway or bridge construction or to school funding. (App. 68). The First Circuit's speculation that the Maine statute may serve a "Medicaid purpose" by warding off impoverishment and thus keeping some Maine residents off the Medicaid rolls (App. 13) could just as readily be used by a state to justify conditioning participation in any federal program upon coerced payments to virtually any social program.

Medicaid is only one of numerous federal programs that match federal funding and oversight with state administration and eligibility determination. *E.g.*, Aid to Families with Dependent Children, 42 U.S.C. § 601 (2001); Community Development Block Grants, 42 U.S.C. § 5301 (2001); Community Services Block Grants 42 U.S.C. § 9901 (2001); Social Services Block Grants, 42 U.S.C. § 1397 (2001); Maternal and Child Health Services Block Grants, 42 U.S.C. § 701 (2001); Alcohol and Drug Abuse and Mental Health Block Grants, 42 U.S.C. § 290cc-21 to cc-35 (2001). It is inconceivable that Congress intends that states shall have license to condition participation in such federal programs on a company's or individual's willingness to make substantial financial contributions to unconnected state programs. Yet states would be free to impose precisely such conditions if Maine is permitted to do so here with respect to the Medicaid program.

II. THE FIRST CIRCUIT DECISION WOULD ALLOW STATES TO ENGAGE IN EXTRATERRITORIAL REGULATION, AND CONFLICTS WITH A DECISION OF THE SEVENTH CIRCUIT AND OTHER PRECEDENTS.

The Commerce Clause, U.S. Const. art. I, § 8, cl. 3, both evidences a grant of power to Congress directly limits the powers of the states. *Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992) (citing authorities). From the earliest days of the Republic, it has been understood that the Commerce Clause encompassed *territorial* limitations on a State's powers. Thus, Chief Justice Marshall in *Gibbons v. Ogden*, 22 U.S. 1, 194 (1824), distinguished between commerce consigned to federal authority by the Commerce Clause and "commerce, which is completely internal [to a state], which is carried on between man and man in a State, or between different parts of the same State." *See also Mayor of New*

York v. Miln, 36 U.S. 102, 133 (1837) ("If we look at the place of [the challenged New York statute's] operation, we find it to be within the territory, and therefore, within the jurisdiction of New York."); *Thurlow v. Commonwealth of Massachusetts*, 46 U.S. 504, 583 (1847) (*The License Cases)*, ("a State [may] regulate commerce within its own limits.")(separate opinion of Chief Justice Taney).

This Court has long recognized that states lack authority to regulate transactions occurring outside their territorial limits. "Laws have no force of themselves beyond the jurisdiction of the state which enacts them, and can have extraterritorial effect only by the comity of other states." *Huntington v. Attrill*, 146 U.S. 657, 669 (1892); *accord New York Life Ins. Co. v. Head,* 234 U.S. 149, 161 (1914) ("[I]t would be impossible to permit the statutes of Missouri to operate beyond the jurisdiction of that state and in the state of New York . . . This is so obviously the necessary result of the Constitution that it has rarely been called into question . . .").

This Court's modern Commerce Clause jurisprudence has repeatedly recognized and applied these precepts to forbid state efforts to control the prices paid in out-of-state transactions. *E.g., Baldwin v. G.A.F. Seelig, Inc.* 294 U.S. 511, 521 (1935) (a state "has no power to project its legislation into [another state] by regulating the price to be paid in that state for [products] acquired there"); *Healy v. The Beer Institute,* 491 U.S. 324, 336 (1989) ("a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature. The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State."); *see generally* 1 Laurence H. Tribe, *American*

Constitutional Law, § 6-12 at 1098 (3d ed. 2000)(referencing "the *per se* principle against extraterritorial state regulation").

These bedrock principles are of great significance to the Chamber's members, which often conduct business in multiple states, and whose operations would be seriously impeded if states were permitted to impose regulatory requirements applicable outside their borders.

The district court was clearly correct that Maine "cannot legislate the amounts that out-of-state manufacturers obtain when they sell to pharmaceutical wholesalers or distributors out-of-state." (App. 59). Yet legislating the price received by the drug company for its out-of-state sales transaction is what "Maine has tried to do here." (*Id.)* As the district court aptly observed, "whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced [by the mandatory rebate] when the drug comes to Maine." (App. 66). Maine is not buying or financing the purchase of the drugs (App. 20); it is instead dictating the price to be received in third-party transactions. Its use of "rebates" to achieve that end, while perhaps innovative, cannot mask the ultimate result.

The prices drug companies charge in their out-of-state sales to wholesalers and distributors likely do have an impact upon the Maine residents who ultimately purchase those drugs. But "[a] State does not acquire power or supervision over the internal affairs of another State merely because the welfare and health of its own citizens may be affected...." *Bigelow v. Virginia*, 421 U.S. 809, 824-25 (1975); *accord Seelig*, 294 U.S. at 523-24. Thus, irrespective of impact, a state may neither "proscribe[]" nor "regulate[]"activities in another state. *Bigelow*, 421 U.S. at 822-23. *Accord Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) ("The Commerce Clause ... precludes the application of a state statute to

commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State.").

The rule could hardly be otherwise; while Maine is dissatisfied with the prices charged in out-of-state drug transactions, other states may be equally unhappy with the prices at which wheat is sold by farmers to grain depots in Kansas, or at which computers are sold to wholesalers in California. Yet surely these other states cannot dictate the price at which those out-of-state sales take place, nor require that a "rebate" be paid to them by the farmer or manufacturer if the products ultimately reach their citizens.

The Maine Rx Act is therefore unconstitutional, insofar as it attempts either to condemn as "unconscionable" the price charged in out-of-state transactions, or to require that a "rebate" be paid by the manufacturer in order to reduce that price. Indeed, Respondent did not even seek to appeal the district court's preliminary injunction against the former (*see* n.2 *supra*), and the latter is no less an effort to control out-of-state pricing. Review by this Court is necessary in order that this principle be clarified.

The appellate court was mistaken to treat the Maine Rx Act as one that regulates activities within the state. (App. 24). While an activity within the state—the sale by a retailer to a Maine resident—triggers the operation of the statute, no obligations are imposed upon either party to that transaction. The target of the regulation is the out-of-state manufacturer, and its purpose and effect is the extraction from that manufacturer of a rebate on the amount it received in an out-of-state transaction. If, as is surely the case, it would be unconstitutional for Maine to decree that Florida orange growers may not be paid more than fifty cents a pound by Florida juice processors, then it is no less unconstitutional for

Maine to demand that the Florida processor pay Maine citizens a "rebate" sufficient to lower that price to fifty cents on juice re-sold by a retailer in Maine.

The First Circuit also erred in concluding that no Commerce Clause violation was present because the amount of the rebate is purportedly the subject of "negotiation".[3] The mandatory nature of the rebate,[4] coupled with the coercive threat of prior authorization, belie any notion that this is a voluntary program. Simply stated, drug companies have no leverage: If they do not agree to pay the rebates requested by Respondent, their drugs become subject to prior authorization within the Medicaid program. And, even assuming that the Commissioner would be flexible as to the exact amount of the rebate, conduct otherwise violative of the Commerce Clause cannot not salvaged by arguments as to the precise dollar amount of the impact. *Cf. Camps Newfound/Owatonna, Inc., v. Town Of Harrison, Maine*, 520 U.S. 564, 581 n.15 (1997) ("there is no 'de minimis' defense to a charge of discriminatory taxation under the Commerce Clause")(*citing Fulton Corp. v. Faulkner*, 516 U.S. 325, 333 n.3 (1996)).

The First Circuit decision is in direct conflict with *Dean Foods Co. v. Brancel*, 187 F.3d 609 (7th Cir. 1999). That case involved a Wisconsin statute that forbade the payment of "volume premiums" to Wisconsin dairy farmers supplying purchasers with large quantities of milk. While the

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[3] The Maine Commissioner of Human Services is directed to use his "best efforts" to achieve a rebate payment at least as great as that required by Medicaid. Me. Rev. Stat. Ann. tit. 22, § 2681(3)(4).

[4] The Maine Rx Act provides that a drug manufacturer "*shall* enter into a rebate agreement with the department for this program." Id. at § 2681(3)(emphasis added).

First Circuit upheld the Maine Rx Act on grounds that it was not an obstacle to the programs of other states, discriminatory, or protectionist (App. 24-25), the same was true for the Wisconsin statute. That statute did not interfere with any other state's dairy pricing regimes; it did not treat differently in-state and out-of-state purchasers; and it did not protect Wisconsin farmers from out-of-state competition.[5]

Nonetheless, the Seventh Circuit struck down the statute insofar as it purported to apply to sales transactions by Wisconsin farmers that took place outside Wisconsin. In so doing the court relied upon the "long line of cases holding that states violate the Commerce Clause by regulating or controlling commerce occurring wholly outside their own borders," and "the long-established core principle that a statute or regulation that violates the extraterritoriality ban is per se invalid." *Dean Foods*, 187 F.3d at 615-16 (citations omitted).[6]

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[5] Indeed, the Wisconsin statute actually made Wisconsin farmers *less* competitive *vis-à-vis* farmers in neighboring states; the statute made Wisconsin milk *less* attractive to purchasers who "[f]or efficiency reasons . . . prefer[] to purchase from milk producers with large herds." *Dean Foods Co. v. Brancel*, 187 F.3d 609, 611 (7th Cir. 1999).

[6] To be sure, the Commerce Clause is *also* concerned with protectionism and discrimination and forbids state regulation so aimed irrespective of whether its foci are within the state. *E.g., West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186 (1994) (striking down state law imposing an assessment on all milk sold in the state and its distribution to in-state farmers only); *Philadelphia v. New Jersey*, 437 U.S. 617 (1978) (striking down state law forbidding the disposal of out-of-state waste in New Jersey landfills). But the mere fact that the dormant Commerce Clause also serves these (...continued)

Because the purchases of milk at issue were found to have transpired outside Wisconsin—as is the case with the drug sales at issue here (App. 60)—they were beyond that state's regulatory reach. *See also Louisiana Dairy Stabilization Board v. Dairy Fresh Corp.*, 631 F.2d 67 (5th Cir. 1980) (out-of-state sales of products ultimately consumed in Louisiana could not, consistent with the Commerce Clause, be subjected to Louisiana's three-cent assessment on milk). At that point, it is not a question of balancing of interests (*cf.* App. 25-27); once it is determined that the statute "burdens out-of-state transactions, there is nothing to be weighed . . ." *Edgar v. MITE Corp.*, 457 U.S. at 644.

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functions in no way limits its role as a bar to extraterritorial state regulation.

CONCLUSION

The First Circuit, which itself described this as a "close case" (App. 28), erred in its decision and in so doing put itself in conflict with other circuits and caused damage to important Supremacy and Commerce Clause principles. The petition for certiorari should be granted.

Respectfully submitted,

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(4)

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No. 01-188

IN THE
Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,
Petitioner,

v.

KEVIN CONCANNON, Commissioner, Maine Department of Human Services; and G. STEVEN ROWE, Attorney General of Maine,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION, ALLIED EDUCATIONAL FOUNDATION, KIDNEY CANCER ASSOCIATION, THE SENIORS COALITION, and THE 60 PLUS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTIONS PRESENTED

1. Does the federal Medicaid statute, 42 U.S.C. § 1396, *et seq.*, allow a state to use authority under that statute to compel drug manufacturers to subsidize price discounts on prescription drugs for non-Medicaid populations?

2. May a State circumvent the Commerce Clause prohibition against regulating or taxing wholly out-of-state transactions by requiring an out-of-state manufacturer, which sells its products to wholesalers outside the State, to pay the State each time one of its products is subsequently sold by a retailer within the State?

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National Conference of State Legislatures, *2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation*, at http://www.ncsl.org/programs/health/drugdisc01.htm (updated August 24, 2001) 8

INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF)[1] is a non-profit public interest law and policy center with supporters in all 50 states, including many in Maine. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. To that end, WLF has appeared before numerous federal and state courts in cases raising issues arising under the dormant Commerce Clause. *See, e.g., National Foreign Trade Council v. Natsios,* 181 F.3d 38 (1st Cir. 1999), *aff'd,* 530 U.S. 363 (2000). WLF recently successfully challenged the constitutionality of Food and Drug Administration restrictions on commercial speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000).

The Allied Educational Foundation (AEF) is a non-profit charitable and educational foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

The Kidney Cancer Association is a patient and survivor-led voluntary health agency pursuing the goal of a world without kidney cancer through research, education, and advocacy.

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, contributed monetarily to the preparation and submission of this brief.

The Seniors Coalition (TSC) is a non-profit, non-partisan education and issue advocacy organization that represents the interests and concerns of America's senior citizens at both the state and local levels. TSC's mission is to give America's seniors a real voice in government to enact public policies that promote and protect their quality of life and economic security. Founded in 1989, TSC has grown to nearly 4 million members; its advocacy includes a wide range of issues important to seniors, including Social Security, Medicare, long-term care, generic drug access, and tax reform.

The 60 Plus Association is a Virginia-based seniors' advocacy group devoted to the free market, free enterprise system. 60 Plus is opposed to price controls on prescription drugs because: (1) they stifle pharmaceutical research leading to the medical miracles enabling seniors to live longer and better and stay out of hospitals; and (2) they result in shortages, as evidenced by the shortcomings of the Canadian health care system.

Amici are concerned that the Maine Rx Program, if allowed to take effect, will have long-term adverse effects on health care in this country. By interfering with the free market in pharmaceutical sales, the Program threatens to discourage research and development of new, life-saving drugs and to Balkanize what is now an efficient national market.

Amici also filed a brief in this case when it was before the appeals court. *Amici* are filing this brief with the consent of all parties. The written consents are on file with the Clerk of the Court.

STATEMENT OF THE CASE

In the interests of brevity, WLF hereby adopts by reference the Statement of the Case contained in the Petition.

In brief, the Pharmaceutical Research and Manufacturers of America ("PhRMA") challenges a Maine law that requires drug manufacturers to subsidize retail drug discounts to Maine residents under a new program called the "Maine Rx Program." Payment of the subsidies is (from a practical standpoint) mandatory, because the State of Maine administers the federal Medicaid program within the State (a program in which all major drug manufacturers participate), and the Maine Rx Program prescribes severe retaliation in connection with Medicaid against any manufacturer that refuses to pay the mandated subsidy. *See* Petition Appendix ("Pet. App.") 70-71.

The Maine RX Program was adopted by the state legislature in May 2000. The law, entitled "An Act to Establish Fairer Pricing for Prescription Drugs" (the "Act"), 2000 Me. Legis. Ch. 786 (S.P. 1026), is codified at 22 M.R.S.A. § 2681. The Act provides that drug manufacturers "shall enter into a rebate agreement" with the Maine Department of Human Services (the "Department") and that the agreement "must require" manufacturers to "make rebate payments to the State each calendar quarter or according to a schedule established by the department." 22 M.R.S.A. § 2681(3). The Act further requires the Department to use "best efforts" to establish rebates at a level equal to or greater than discounts obtained by the federal government in connection with its bulk purchases of prescription drugs. 22 M.R.S.A. § 2681(4). The Act further provides that pharma-

cists in Maine are to sell prescription drugs to Maine residents at substantially discounted prices and that money collected by the State from drug manufacturers under the Maine Rx Program is to be paid to the pharmacists in order to reimburse them for those discounts. 22 M.R.S.A. §§ 2681(5), (6).

The subsidies are required of all drug manufacturers whose products are sold in Maine, even though no drug manufacturers are based in Maine and even though very few of them sell their products to Maine wholesalers. Rather, virtually all prescription drugs that end up in Maine are sold to wholesalers or distributors in transactions that occur outside the State; the wholesalers and distributors make their own arrangements for shipment into Maine. Pet. App. 60. Moreover, as the district court recognized, the rebate program results in a reduction in the wholesale price obtained by manufacturers for each drug that is later sold in Maine, because the amount of a manufacturer's rebate is determined by the quantity of that manufacturer's products sold in Maine. *Id.* at 66.

PhRMA filed suit against the Maine Rx Program in U.S. District Court for the District of Maine. The Complaint alleged that the Program violated the Commerce Clause of the U.S. Constitution by attempting to regulate transactions occurring outside of Maine, and violated the Supremacy Clause by requiring Maine to administer the Medicaid program in a manner that conflicts with federal law.

On October 26, 2000, the district court granted PhRMA's motion for a preliminary injunction against any

efforts by Maine to enforce the payment of rebates under the Program. Pet. App. 57-72. Initially, the court rejected Maine's argument that the Maine Rx Program entailed nothing more than the exercise of power derived from Maine's role as a participant in the prescription drug market, and thus that the Program should be exempt from Commerce Clause scrutiny under the "market participation" exception. The court said that that exception does not immunize State efforts to leverage power derived from one market in which it participates (in this case, the purchase of drugs under the Medicaid program) in order to regulate a market in which it does not participate (in this case, the market for prescription drugs purchased outside of Medicaid). *Id.* at 61-64.

The court went on to find that the Program violated the Commerce Clause because it attempted to regulate transactions taking place solely outside the State. *Id.* at 64-66. "Maine may have power over what pharmacies later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the price paid in earlier transactions in other states." *Id.* at 65. The court held that the Program was invalid without regard to whether the Program could be said to discriminate against out-of-staters in favor of in-staters. *Id.* at 66.

The court also held that the Program was invalid under the Supremacy Clause because it was impliedly preempted by federal Medicaid law. *Id.* at 66-70. The court found that the Program stood "as an obstacle to the accomplishment and execution of the Congressional objectives of federal Medicaid," because it made it more difficult for certain drugs to be prescribed to Medicaid recipients. *Id.* at 68.

Having found that PhRMA was "overwhelming[ly]" likely to prevail on the merits and that the other relevant factors also favored PhRMA, the court granted a preliminary injunction against enforcement of the Program's rebate scheme. *Id.* at 72.

The U.S. Court of Appeals for the First Circuit reversed and vacated the preliminary injunction. *Id.* at 1-53. The appeals court initially determined that the Program was not preempted by federal law, finding "no conflict between the Maine Act and Medicaid's structure and purpose." *Id.* at 11. While noting that the Program threatens imposition of a "prior authorization" requirement on manufacturers that do not participate in the Act's price control program, the court held that the Medicaid statute does not concern itself with a State's motivation in choosing to impose such a requirement -- and thus that Maine's use of its "prior authorization" power as a club to ensure manufacturer participation does not conflict with any purpose of the Medicaid law. *Id.* at 12-13. The court said that the Program actually "furthers Medicaid's aim of providing medical services to those" otherwise unable to meet the costs of necessary medical services but who are not poor enough to qualify for Medicaid. *Id.* at 13.

The appeals court also held that the Program did not violate the Commerce Clause. *Id.* at 17-27. As did the district court, the appeals court rejected Maine's argument that it was exempt from Commerce Clause restraints by virtue of its status as a "market participant." *Id.* at 20. The court nonetheless rejected PhRMA's Commerce Clause challenge, finding that "the Maine Act does not impose direct controls on a transaction that occurs wholly out-of-state," *Id.* at 23. The court reasoned, "Simply because the

manufacturers' profits might be negatively affected by the Maine Act . . . does not necessarily mean that the Maine Act is regulating those profits." *Id.* The court held that whatever burdens the Program imposed on interstate commerce were not "clearly excessive" in relation to the benefits derived by Maine. *Id.* at 25-27.

REASONS FOR GRANTING THE PETITION

Amici curiae fully support the arguments put forth by PhRMA regarding why grant of the Petition is warranted. They write separately in order to emphasize the significant public importance of the issues raised by this case. The price of prescription drugs is of great importance to virtually all Americans; high prices may deprive some consumers of the ability to afford proper medical care, but artificially low prices may deprive *all* citizens of optimal care by reducing the financial incentives necessary to ensure that new, life-saving medical products continue to be developed.

Numerous States either have already enacted or are on the verge of enacting legislation designed to control the price of prescription drugs. That legislation has spawned numerous lawsuits challenging various aspects of these price control schemes. In light of those challenges -- which have led to conflicting court decisions -- guidance from the Court is urgently needed. In particular, guidance is needed regarding whether price controls are appropriately imposed on an *ad hoc*, state-by-state basis or whether, in light of the Commerce Clause and relevant federal statutes, the issue is more appropriately addressed on a nationwide basis.

I. REVIEW IS WARRANTED IN LIGHT OF THE MAJOR IMPORTANCE OF THE QUESTIONS PRESENTED TO THE DELIVERY OF HEALTH CARE IN THIS COUNTRY

Rising use of prescription drugs by consumers has led in recent years to a significant increase in total expenditures for prescription drugs in this country. That increase in turn has led to efforts in numerous States to control prescription drug prices.

According to the National Conference of State Legislatures (NCSL), 30 states have now adopted some type of program designed to control prescription drug prices. *See* NCSL, *2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation, at* http://www.ncsl.org/programs/health/drugdisc01.htm (updated August 24, 2001). New legislation mandating discount programs, bulk purchasing programs, expanded manufacturer rebates, and/or price controls "are being considered in at least 40 states." *Id.* The pace at which such legislation is being considered has quickened following the First Circuit's rejection of PhRMA's facial challenge to the Maine price control Program. The Center for Policy Alternatives ("CPA") reports that the First Circuit's decision has "reignited efforts to lower prescription drug prices at the state level," with legislation modeled after the Maine Rx Program pending in 27 states. CPA, *States Poised to Lower Prescription Drug Prices as First Circuit Court of Appeals Rules Against PhRMA,* (Summer 2001) *at* www.stateaction.org/alternatives/altbody2.cfm?volume=v9no3&artnumber=4 (visited August 27, 2001).

In light of the large number of state statutes being adopted in this area, the need for the Court's guidance regarding the constitutionality of such legislation is readily apparent. The challenges raised by PhRMA are substantial; it prevailed in the district court, and the First Circuit conceded that this was a "close case." Pet. App. 28.

Nor are the issues raised by PhRMA ones that would benefit from additional "percolation" in the lower courts. As the district court recognized, the record in this case "is essentially undisputed." *Id.* at 72. Accordingly, although the case is before the Court in connection with a motion for a preliminary injunction, there is little reason to believe that delaying consideration of the case until after entry of a final judgment would sharpen the issues by providing the Court with a more complete factual record. Moreover, the Court is well-experienced in dealing with claims that States are violating the Commerce Clause by regulating commerce extraterritorially, and thus would benefit little by awaiting additional court of appeals review before taking up the issue.

Amici are particularly concerned that additional delays in the Court's consideration of PhRMA's claims will lead to massive disruptions of the American health care system. The experience in Canada and elsewhere is that price controls inevitably lead to shortages both in drugs and medical services -- without having any significant effect on costs. *See* "Prescription Drug Costs: Has Canada Found the Answer?," National Center for Policy Analysis, Brief Analysis No. 323 (May 19, 2000). That study found:

> While some drugs do cost less in Canada, others don't. Furthermore, large numbers of Canadians come to the

United States to buy drugs because so many drugs are not available at any cost in Canada. The Canadian government purposely restricts the overall availability of prescription drugs through a combination of lengthy drug approval process and oppressive price controls. The result is that patients are often harmed.

* * *

Through limiting the availability of prescription drugs and controlling prices of those that are available, Canada has succeeded only in preventing Canadians from obtaining drugs that might have reduced hospital stays and expensive medical procedures. Despite prices on some individual drugs that are lower than in the United States, Canada has been unable to hold down the overall cost of either prescription drugs or other health care. The result is a lower standard of health care at a higher cost than Canadian patients and taxpayers have a right to expect.

Id.

Delays in consideration of PhRMA's claims could also disrupt health care delivery if, as is likely, new price control legislation leads to diminished research and development ("R&D") and, ultimately, to decreased development of new, life-saving drugs. On average, it costs anywhere from $500 million to $1 billion in R&D costs to get a drug approved for use in the United States. *Drug Price Controls: A "Cure" Worse Than the Disease,* The Independent Institute (2000). Basic economics dictate that pharmaceutical companies must recover all their costs, plus a reasonable profit, in order to

spur them to continue to develop new medicines. As one expert has noted:

> Any attempt to regulate pharmaceutical prices on the basis of cost. . . will be imprecise and arbitrary. Regulators are tempted to set prices to cover only those costs that are clearly attributable to the delivery of particular drugs to particular market segments. That narrow focus tends to result in prices that are too low to cover R&D, therefore stifling innovation and competition.

Patricia M. Danzon, "Making Sense of Drug Prices," 23 REGULATION at 62-63 (2000).

Whether prescription drug price controls are good public policy is not, of course, the issue before the Court. Nonetheless, in light of the very significant potential impact on health care delivery of the Maine Rx Program and similar laws proposed in other States, immediate review of the issues raised by PhRMA is warranted.

II. THE FIRST CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S "DORMANT" COMMERCE CLAUSE CASE LAW

The Court should grant review for the additional reason that the First Circuit's decision so clearly conflicts with this Court's "dormant" Commerce Clause case law.

The record is uncontested that virtually all prescription drugs sold in Maine were initially sold by drug companies to wholesalers in connection with transactions that took place

wholly outside the State of Maine. Yet, the Maine Rx Program attempts to regulate such wholesale transactions by reducing the wholesale price by the amount of the rebate that manufacturers are required to pay to the State. The Court has held on numerous occasions that such State efforts to exert extraterritorial control over sales transactions lacking any significant nexus with the State constitute a *per se* violation of the Commerce Clause.

As the district court held, "bedrock principles concerning the territorial limits of a state's power" prohibit a State from attempting to "extend its authority to out-of-state manufacturers" in this manner. Pet. App. 64-65. The Court has repeatedly held that a State's efforts to control commerce occurring wholly outside the boundaries of the State are *per se* invalid under the dormant Commerce Clause. The Court has explained:

> Taken together, our cases concerning the extraterritorial effects of state economic regulation stand at a minimum for the following propositions. First, the Commerce Clause precludes the application of a state statute to commerce that takes place outside of the State's borders, whether or not the commerce has effects within the State. [Citations omitted.] . . . Second, a statute that directly controls commerce wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature.

Healy v. Beer Institute, 491 U.S. 324, 336 (1989). In *Healy*, the Court struck down a Connecticut law that required liquor

wholesalers to affirm that their prices were no higher than the prices at which their products were sold in neighboring states, because the law had the inevitable impact of controlling wholesale prices in those neighboring States. *Id.* at 338.

Similarly, the Court struck down as a *per se* Commerce Clause violation a New York law that prohibited the sale in New York of milk which had been sold by milk producers in other states for less than New York's minimum producer price. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935). Justice Brandeis wrote for the Court in that case:

> New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there. So much is not disputed. New York is equally without power to prohibit the introduction within her territory of milk of wholesome quality acquired in Vermont, whether at high prices or low ones.

Id. at 522.

The First Circuit attempted to distinguish *Healy* and *Baldwin* by asserting that the Maine Rx Program does not operate extraterritorially. Pet. App. 22-23. That assertion cannot be squared with the uncontested facts. The parties agree that the amount of the rebate is tied directly to the volume of a manufacturer's drugs ultimately sold within Maine. Accordingly, each dollar of the rebate can be traced to a specific wholesale transaction that took place wholly outside Maine. The First Circuit is correct, of course, that Maine does not dictate to manufacturers the precise whole-

sale price at which they must sell their drugs. But it cannot seriously be disputed that Maine is directly regulating those wholesale transaction: it is directing that the net wholesale price be reduced by the amount of the Maine Rx Program rebate.

The Commerce Clause does not, of course, constrain Maine's power to impose price controls on retail sales occurring within the State. But Maine has chosen not to pursue that path. Instead of imposing economic burdens on in-state pharmacists, it has attempted to impose those burdens on out-of-state drug manufacturers who, for the most part, have not engaged in any economic transactions within the State. Maine's efforts to regulate out-of-state drug sales are at least as "direct" as New York's efforts in *Baldwin* to regulate out-of-state milk sales, or Connecticut's efforts in *Healy* to regulate out-of-state liquor sales. Yet the First Circuit rejected the Commerce Clause challenge to the Maine Rx Program, while this Court struck down the factually indistinguishable programs in *Baldwin* and *Healy* as *per se* Commerce Clause violations. The Court should grant review in this case to address the conflict between the First Circuit's decision and this Court's Commerce Clause case law.

III. THE FIRST CIRCUIT'S DECISION CONFLICTS WITH A D.C. CIRCUIT DECISION REGARDING THE MEDICAID LAW'S PREEMPTIVE EFFECT

The Court should grant review for the additional reason that the First Circuit's decision conflicts with a decision from the U.S. Court of Appeals for the District of Columbia

Circuit regarding the preemptive effective of federal Medicaid law.

Although the Maine Rx Program is independent of the State's administration of Medicaid, the Program uses a provision of Medicaid as a club to ensure manufacturer participation in its rebate program, the "prior authorization" provision. When subjected to prior authorization, a drug may not be dispensed to a Medicaid beneficiary without the approval of the State Medicaid administrator. The Maine Rx Program threatens that all of a manufacturer's drugs will be subject to Medicaid prior authorization if the manufacturer fails to participate in the rebate program. Because all pharmaceutical manufacturers derive significant income from Medicaid and because it is well accepted that any company whose drugs are subjected to Medicaid prior authorization will suffer significant sales loss, manufacturers are, for all intents and purposes, forced to participate in the Maine Rx Program. As the district court found, the Maine Rx Program cannot realistically be deemed "voluntary."

Although it acknowledged that the Maine Rx Program does not serve Medicaid recipients, the First Circuit found nothing objectionable in this scheme. The court discerned nothing in federal Medicaid law to indicate that Congress frowned on States using the powers delegated to them as local Medicaid administrators in order to effectuate a prescription drug price control program for non-Medicaid recipients. Pet. App. 12-13. Accordingly, the appeals court rejected PhRMA's argument that the Maine Rx Program is preempted under the Supremacy Clause. *Id.*

The First Circuit decision directly conflicts with a decision from the U.S. Court of Appeals for the District of Columbia Circuit on this preemption issue. At issue in *Pharmaceutical Research and Manufacturers of America v. Thompson,* 251 F.3d 219 (D.C. Cir. 2001), was a State of Vermont program imposing price controls on pharmaceuticals sold to lower-income Vermonters who did not qualify to receive Medicaid. Similar to the Maine Rx Program, the Vermont program relied on a Medicaid provision to force manufacturers to comply with the program.[2] The D.C. Circuit struck down the Vermont scheme, finding that Congress had not intended the Medicaid provision upon which Vermont and HHS relied (the rebate requirement) to be used to effectuate price controls for non-Medicaid purchasers. *Thompson*, 251 F.3d at 226. The D.C. Circuit did *not* suggest that any federal law explicitly prohibited the Vermont scheme; rather, the court reasoned that the scheme was unauthorized because it did not serve any purposes of the Medicaid laws. The court said that Congress added the rebate requirement to reduce the cost of the Medicaid program, not to permit price controls to be imposed on pharmaceutical sales to non-Medicaid recipients. *Id.*

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[2] The provision used by Vermont is one that requires pharmaceutical manufacturers to rebate a portion of the price of their drugs sold to Medicaid recipients, as a condition for participating in Medicaid. *See* 42 U.S.C. § 1396r-8(a)(1). Vermont sought to extend the rebate requirement to cover drugs sold to 70,000 Vermont residents who were not eligible for Medicaid; indeed, the U.S. Department of Health and Human Services had approved Vermont's request to expand the rebate requirement.

The conflict between *Thompson* and the First Circuit decision could hardly be more direct. Both cases turned on whether, in the absence of an explicit statutory prohibition, a State may leverage its power derived from its status as the local Medicaid administrator to impose price controls on prescription drugs sold to those not covered by Medicaid. The First Circuit said yes; the D.C. Circuit said no. That the cases required analysis of different sections of the Medicaid laws does not make the conflict any less direct. In the final analysis, each appellate court based its decision on whether Congress intended to permit use of a Medicaid administrator's enforcement tools to serve non-Medicaid purposes; they arrived at opposite conclusions regarding that issue.[3] The Court should grant review in order to resolve the conflict.

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[3] The First Circuit made a half-hearted assertion that the Maine Rx Program does, in fact, further Medicaid's aims. Pet. App. 13 (Program furthers the aim of "providing medical services to those whose income and resources are insufficient to meet the costs of necessary medical services" and, by making prescription drugs more accessible to the poor, it may reduce total Medicaid expenditures by preventing onset of more serious diseases). However, that assertion does nothing to distinguish the decision below from *Thompson*. Indeed, those same assertions could have been made even more plausibly in *Thompson* because the Vermont price control program (unlike the Maine Rx Program) imposed strict income limitations on eligibility.

CONCLUSION

Amici curiae respectfully request that the Court grant the Petition.

Respectfully submitted,

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PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

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CONCANNON, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether a Maine statute providing for affordable prescription drugs, which penalizes companies that won't drop prices for uninsured residents, violates the Constitution's Commerce Clause.

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INTEREST OF AMICUS CURIAE

Pacific Legal Foundation (PLF) was founded 29 years ago and is widely recognized as the largest and most experienced nonprofit legal foundation of its kind. PLF litigates matters affecting the public interest at all levels of state and federal courts and represents the views of thousands of supporters nationwide. PLF is an advocate for limited government, individual rights, and free enterprise and believes public officials must be respectful of the constitutional limitations on federal power. PLF established a Free Enterprise Project in which we submit amicus briefs in cases impacting America's economic vitality. For example, PLF filed amicus briefs in *Chevron, U.S.A., Inc. v. Echazabal*, 122 S. Ct. 2045 (2002), and *Adams v. Florida Power Corp.*, 122 S. Ct. 643 (2001). PLF believes that Maine's statutory threat to impose pharmaceutical price controls overstepped the bounds of its sovereignty and intrudes unconstitutionally on the American national marketplace.[1]

STATEMENT OF THE CASE

In May, 2000, Maine enacted an Act to Establish Fairer Pricing for Prescription Drugs, thus creating the Maine Rx Program. The program, funded wholly by "rebates" from drug manufacturers, subsidizes retail prescription drug purchases for Maine citizens. Me. Rev. Stat. tit. 22, § 2681(3)-(5) (2001). The law provides that manufacturers will make payments to the State based on the quantity of drugs dispensed to Maine Rx participants by retailers. Me. Rev. Stat. tit. 22, § 2681(4).

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[1] Pursuant to this Court's Rule 37.3(a), all parties have consented to the filing of this brief. Letters evidencing such consent have been filed with the Clerk of the Court.

Pursuant to Rule 37.6, Amicus Curiae affirms that no counsel for any party authored this brief in whole or in part and that no person or entity made a monetary contribution specifically for the preparation or submission of this brief.

Using the Maine Rx program, residents can purchase drugs from retail pharmacies at discounts funded by the rebates. Me. Rev. Stat. tit. 22, § 2681(5). The "rebate agreements" are not freely entered into—the Act mandates that manufacturers "shall" subsidize Maine Rx drugs. Me. Rev. Stat. tit. 22, § 2681(3). The Act enforces Maine Rx provisions using Medicaid regulatory powers to require "prior authorization" by state officials for prescriptions dispensed to Medicaid patients. Me. Rev. Stat. tit. 22, § 2681(7). Prior authorization creates a procedural obstacle to Medicaid patients' access to listed drugs, which in turn reduces Medicaid-funded purchases of those drugs.

In addition, the Act provides that failure to comply is considered a violation of the Maine Unfair Trade Practices Act, which allows a private right of action and additional penalties. Me. Rev. Stat. tit. 10, §§ 212-13. Finally, and most ominously, the Act contemplates imposing direct price controls on retailers in 2003 if the Maine Rx program does not lower drug prices to the State's satisfaction. Me. Rev. Stat. tit. 22, § 2693(1)(B).

The Pharmaceutical Research and Manufacturers of America sued to invalidate Maine Rx on the grounds that the Act violates the dormant Commerce Clause and was preempted by the Medicaid statute under the Supremacy Clause. The district court agreed but the First Circuit Court of Appeals reversed, finding that Maine Rx only regulates in-state activities and sets forth prior authorization procedures consistent with those permitted by Medicaid law. The First Circuit held that the Act does not regulate out-of-state prices, either on its face or by its effect. *Pharmaceutical Research and Manufacturers of America v. Concannon (PhRMA)*, 249 F.3d 66, 81 (2001). Furthermore, the court held that there is nothing in the Act tying the in-state prices of prescription drugs to out-of-state prices, or imposing controls on wholly out-of state transactions. *Id.* at 81-82. On a facial challenge of the statute, the court below refused to hold that the "negotiators' " potential for abuse actually

regulates drug prices. *Id.* at 82. The court thus concluded that while Maine Rx regulates a large amount of in-state commerce, there is no actual extraterritorial reach, and the Act is not per se invalid. *Id.*

The First Circuit also reviewed the act under the balancing test from *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970): "Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." Balancing the increased access to prescription drugs for residents of Maine against the drug manufacturers' possible loss of profits, the court held that the "putative local benefits" clearly outweigh the incidental "effects on interstate commerce." *PhRMA*, 249 F.3d at 83-84. Thus, the First Circuit found no dormant Commerce Clause violation under either the strict per se test or the lesser *Pike* balancing test.

On June 28, 2002, this Court granted certiorari.

SUMMARY OF ARGUMENT

The Constitution "was framed upon the theory that the peoples of the several states must sink or swim together, and that in the long run prosperity and salvation are in union and not division." *Baldwin v. G. A. F. Seelig, Inc.*, 294 U.S. 511, 523 (1935). That is, individual residents of the several States are citizens of a nation, and some state statutes are incompatible with this ideal. Stone, Geoffrey R., et al., *Constitutional Law* 293-94 (3d ed. 1996). Furthering this ideal, the Commerce Clause of the Constitution created an "area of free trade among the several States." *Associated Indus. of Missouri v. Lohman*, 511 U.S. 641, 650 (1994) (quoting *McLeod v. J. E. Dilworth Co.*, 322 U.S. 327, 330 (1944)). Despite these benefits of free trade, states have incentives to enact regulations or taxes that impose costs on other states while the benefits remain in the

state. Posner, Richard A., *Economic Analysis of Law* § 25.3, at 699 (5th ed. 1998). This is precisely what Maine seeks to accomplish—lower drug prices for its own residents at the expense of residents outside the state's borders.

Case law interpreting the dormant Commerce Clause has never approached a problem precisely like that posed by Maine Rx. In this case, the state imposed a facially-neutral statutory scheme that has the effect of regulating out-of-state transactions to obtain an economic advantage for its own residents. While pharmaceutical consumers living in Maine enjoy lower drug prices, the pharmaceutical companies' natural reaction to increase drug prices for other consumers outside the state presents a potentially significant impact on interstate commerce. Maine's manipulation of interstate commerce for the economic advantage of its residents undercuts the national free-market policies underlying the dormant Commerce Clause and is akin to the protectionism traditionally held unconstitutional under that provision.

America's history is based on our willingness to take risks, and on free-market support of innovation. In considering the constitutionality of Maine Rx, the Court should act to protect the American common market in pharmaceuticals—the world leader in this critical industry. The American common market in pharmaceuticals is a worldwide success, benefitting hundreds of millions of people. Drug manufacturers reinvest much of their profits to fund the high risk research essential to developing innovative new drugs and therapies. Controlling drug prices limits pharmaceutical research and development (R&D), thus delaying or diminishing the life-enhancing possibilities that such research will yield. The Maine Rx requirements that pharmaceutical companies provide Medicaid-level discounts to all Maine residents or face price controls serve only to benefit Maine drug consumers while this manipulation of interstate commerce will force consumers in other states to face increased drug prices to compensate for

revenue lost in Maine. If Maine carries through on its threat to impose price controls, American patients in general will pay the price in reduced health. For the reasons set forth below, the decision of the First Circuit Court of Appeal should be reversed.

ARGUMENT

I

MAINE RX IS PROTECTIONIST LEGISLATION ENACTED IN VIOLATION OF THE DORMANT COMMERCE CLAUSE

The Commerce Clause provides that "the Congress shall have Power . . . [t]o regulate commerce . . . among the several States . . . ." U.S. Const. art. I, § 8, cl. 3. When the Framers designed the United States Constitution, they included this clause to prevent economic barriers to trade from threatening the new political order. *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 807 (1976) (Commerce Clause designed to help the states form "a cohesive whole" after the revolution). This Court has long held that the flip side of the Commerce Clause—the "dormant" Commerce Clause—forbids State regulation of interstate commerce. *H. P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 537-38 (1949). As Justice Jackson wrote for the Court:

> Our system, fostered by the Commerce Clause, is that every farmer and every craftsman shall be encouraged to produce by the certainty that he will have free access to every market in the Nation, that no home embargoes will withhold his exports, and no foreign state will by customs duties or regulations exclude them.

Id. at 539. The Framers sought to curb interstate exploitation by stronger states and by those with geographic advantages. The Federalist No. 6 (A. Hamilton) (Rossiter ed. 1961);

1 Records of the Federal Convention of 1787 at 19, 164 (M. Farrand ed. 1911).

The fundamental prohibition of the dormant Commerce Clause, as interpreted by the Supreme Court, is against "discrimination"—i.e., "differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter." *Oregon Waste Sys., Inc. v. Department of Envtl. Quality*, 511 U.S. 93, 99 (1994). A state statute that discriminates on its face against out-of-state businesses or goods is "virtually per se unlawful" and must be justified under the "strictest scrutiny," a standard that the state almost never can satisfy. *Id.* at 101; *City of Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978). A state regulation that is not facially discriminatory may nonetheless be unlawful if the burdens it imposes on interstate commerce exceed the benefits. *Pike*, 397 U.S. at 142. The Court only rarely strikes down statutes under this balancing test. Petragnani, Amy M., Comment, *The Dormant Commerce Clause: On Its Last Leg*, 57 Alb. L. Rev. 1215, 1249 (1994) ("The Court is no longer applying the dormant Commerce Clause to overturn state legislation unless the statute is clearly or facially discriminatory.").

This Court's dormant Commerce Clause cases are supposed to follow one of two theories. The first theory is that the dormant Commerce Clause "provide[s] an economic blueprint for the nation's economic functioning," while the second theory purports that the clause "fulfill[s] a political vision of a federal government responsive to the needs of all citizens while at the same time respecting and honoring the institutional interests of the States." Lawrence, Michael A., *Toward a More Coherent Dormant Commerce Clause: A Proposed Unitary Framework*, 21 Harv. J.L. & Pub. Pol'y 395, 411 (1998). In this case, PhRMA argued the economic blueprint theory by analogizing Maine's statute to price affirmation statutes that have been declared unconstitutional by this Court, under a "practical effect" test. Maine, on the other

hand, argued the political vision theory, asserting that the benefits to the state must be weighed against the burden to commerce. Phelps, Whitney Magee, *Maine's Prescription Drug Plan: A Look into the Controversy*, 65 Alb. L. Rev. 243, 255 (2001). Thus, the "economic blueprint" theory maps to the strict per se invalidity test (applied to both extraterritorial reach and to discriminatory legislation) while the "political vision" theory maps to the *Pike* balancing test. These separate lines of inquiry have led to a morass of confusion—even to members of this Court, who describe the analysis as "hopelessly confused," *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 706 (1981) (Rehnquist, J., dissenting), a "quagmire," *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 210 (1994) (Scalia, J., concurring), and "not always . . . easy to follow." *CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69, 87 (1987).

The basic problem is that the two supposedly separate analyses have been blurred, using the language from one test to support a result that purportedly was arrived at using the other test. For example, the Court has struck down facially neutral state statutes that it determines to be discriminatory in effect. In *West Lynn Creamery*, 512 U.S. at 190-91, the Court struck down a Massachusetts milk pricing order that imposed a tax on all milk and used the proceeds to fund a subsidy to in-state milk producers. Although the milk tax was facially non-discriminatory because it applied equally to all milk, the Court invalidated the pricing order based on a "case-by-case analysis of purposes and effects" rather than legal doctrine. *Id.* at 201. In *American Trucking Associations v. Scheiner*, 483 U.S. 266, 286 (1987), the Court struck down facially neutral taxes on trucks based on their "practical effect" of imposing "a cost per mile on appellants' trucks that is approximately five times as heavy as the cost per mile borne by local trucks." *See also Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333, 350-54 (1977). In each case the state statute was neutral on its face, which ordinarily would have resulted in the Court's

applying a balancing test that rarely leads to invalidation of the statute. Instead, the Court looked to the practical effect of the statute and found that it unconstitutionally interfered with free trade. Drahozal, Christopher R., *Preserving the American Common Market: State and Local Governments in the United States Supreme Court*, 7 S. Ct. Econ. Rev. 233, 245 (1999) (*Preserving the American Common Market*).

On top of this confusion comes this case—unlike any other in the dormant Commerce Clause canon. Maine wants lower drug prices for consumers within its border, but does not want Maine taxpayers to pay for the discount via the state treasury. Instead, the state enacts a statutory scheme to shift to the pharmaceutical companies the cost of the marginal difference between the market value of the drugs and the price the state believes is fair. Because those companies are based outside of Maine and engaged in interstate commerce, the state must bear the burden of showing that its regulation does not have the potential to cause significant effects on interstate commerce. One factor the Court should consider is the impact on interstate commerce if Maine's regulation is replicated in other states, regardless of whether that replication is "the sincerest form of flattery" or in retaliation.

A. A Statute Violates the Dormant Commerce Clause If It Is Protectionist, Regardless of Whether It Is Discriminatory

The dormant Commerce Clause preserves "a national market for competition undisturbed by preferential advantages conferred by a State upon its residents or resident competitors." *General Motors Corp. v. Tracy*, 519 U.S. 278, 299 (1997). When states burden commerce outside their borders, they interfere in policy choices of other states or of the federal government or both. If this interference devolves into economic warfare, the ultimate losers will be the smaller and weaker states and those with less favorable geography—like Maine. Collins, Richard B., *Economic Union As a*

Constitutional Value, 63 N.Y.U. L. Rev. 43, 64 (1988) (*Economic Union*). The free-trade objectives incorporated in the dormant Commerce Clause further the efficient allocation of resources within American society, just as free trade among nations helps to further the efficient allocation of resources in the world. Gifford, Daniel J., *Federalism, Efficiency, the Commerce Clause, and the Sherman Act: Why We Should Follow a Consistent Free-Market Policy*, 44 Emory L.J. 1227, 1227-28 (1995).

Indeed, this Court frequently asserts that the dormant Commerce Clause calls for an American "common market." *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 423 (1994); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 293 (1980); *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. at 350; *H. P. Hood,* 336 U.S. at 538. Tying this economic policy to political processes, regulations must allow those primarily affected by the regulation to register their approval or disapproval about the measure through the political process directly by voting. *Southern Pac. Co. v. Arizona ex rel. Sullivan*, 325 U.S. 761, 767 n.2 (1945) ("[T]o the extent that the burden of state regulation falls on interests outside the state, it is unlikely to be alleviated by the operation of those political restraints normally exerted when interests within the state are affected."). Regulations are like other products: when costs are not borne by producers, these costs are disregarded, and producers create more of the products than an efficient market would supply. When costs imposed by legislation are exported outside the state, there is less political pressure to minimize these costs and there is a greater chance that the law will reduce aggregate welfare. *Economic Union*, 63 N.Y.U. L. Rev. at 68.

A common understanding of protectionism is the act of guarding or shielding one's own. *Economic Union*, 63 N.Y.U. L. Rev. at 74 ("Classic protectionism meant shielding domestic producers against competition from imports."). However, the dormant Commerce Clause doctrine

applies to both producer *and consumer* favoritism. *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, 580 (1986) ("Economic protectionism is not limited to attempts to convey advantages on local merchants; it may include attempts to give local consumers an advantage over consumers in other States."). In *Camps Newfound/Owatonna v. Town of Harrison*, 520 U.S. 564, 575-76 (1997), the Court rejected the Town's argument that the dormant Commerce Clause concerns the protection of out-of-state producers only, holding instead that impermissible protection can come both in the form of preferences to local merchants and advantages to local consumers: "[I]t matters little that it is the camp that is taxed rather than the campers. . . . The economic incidence of the tax falls at least in part on the campers . . . ." *Id.* at 580; *see also Philadelphia v. New Jersey*, 437 U.S. at 627 ("[A] State may not accord its own inhabitants a preferred right of access over consumers in other States to natural resources located within its borders.").

Protectionist practices are repugnant simply because they are directly inconsistent with the quest for national unity. O'Grady, Catherine Gage, *Targeting State Protectionism Instead of Interstate Discrimination Under the Dormant Commerce Clause*, 34 San Diego L. Rev. 571, 626-27 (1997) (*Targeting State Protectionism*). Protectionism ought to be targeted as the evil prohibited by the dormant Commerce Clause because it is "hostile in its essence" and likely to cause resentment and invite retaliation. Regan, Donald H., *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, 84 Mich. L. Rev. 1091, 1113-14 (1986). States do not have the right to regulate transactions occurring outside their borders regardless of whether they intend to discriminate against interstate commerce. A state may not purposefully manipulate the channels of interstate commerce to isolate the state from the national economy or

protect resident economic interests from the national market.[2] A protectionist statute purposefully makes use of the state's own borders or the network of the interstate market to improve the position of local residents simply because they are local. *See Targeting State Protectionism*, 34 San Diego L. Rev. at 588.

The Court has applied this anti-protectionist theory in several cases, most frequently those that apply the "per se invalidity" higher level of scrutiny. In *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, the Court invalidated a New York law that set price ceilings for liquor sold in-state based on the seller's lowest price in other states. This Court held that a state law that "directly regulates or discriminates against interstate commerce" will generally be struck down "without further inquiry." *Id.* at 579. The Court presumed that the law improperly burdened interstate commerce by forcing up the price of liquor in other states, particularly smaller ones. *Id.* at 582-84. In other words, New York was exploiting market power as a large consumer to gain advantage at the expense of smaller states. The Court was willing to assume the law had these effects, even in the absence of proof. *Id.*[3]

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[2] This Court need not decide whether the protectionism or discrimination was deliberate. *See Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. at 352 ("[W]e need not ascribe an economic protection motive to the North Carolina Legislature to resolve this case . . . ."); *Pike*, 397 U.S. at 145-46 (finding intent irrelevant); *Halliburton Oil Well Cementing Co. v. Reily*, 373 U.S. 64, 72 (1963) (acknowledging that state tax law at issue may have discriminated accidentally but striking law down anyway). Most of the dormant Commerce Clause opinions say nothing about intent.

[3] The Court was unwilling to "indulg[e] the . . . assumption" that the state would be sensitive to Commerce Clause concerns in the implementation of its statute. "The protections afforded by the

(continued...)

Similarly, in *Healy v. Beer Institute*, 491 U.S. 324, 336 (1989), the Court held:

> [The] Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, . . . [and] a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority, and is invalid . . . .

The critical inquiry in determining a state law's validity is whether it has the "practical effect" of regulating commerce occurring outside the state's borders. In *Healy* and *Brown-Forman*, this Court held that a State may not regulate in a manner that sets prices on transactions between buyers and sellers in other States, to ensure a more favorable price structure for domestic consumers at the expense of consumers in other States. Under these cases, the laws were subject to a "virtually per se rule of invalidity" under the dormant Commerce Clause. It did not matter if the statute did not on its face regulate out-of-state transactions.

In our federal system, uniform national standards, where appropriate, are for Congress to set. As the Founders knew and this Court's dormant Commerce Clause jurisprudence has recognized, allowing one state to impose its laws on commerce nationwide would place commerce at the mercy of local, parochial interests and create an anarchy of conflicting state legal regimes which would destroy commercial confidence and create hostility between the states. *See, e.g., C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. at 406 (O'Connor, J.,

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[3] (...continued)
Commerce Clause cannot be made to depend on the good grace of a state agency." *Id.* at 582 n.5.

concurring) (differing state regimes regulating flow of solid waste would result in "the type of balkanization the Clause is primarily intended to prevent"). State laws regulating corporate takeovers, for example, restrain share sales occurring entirely outside the regulating state. They prevent some takeovers altogether and raise costs of others substantially. This Court struck down one such law in *Edgar v. MITE Corp.*, 457 U.S. 624 (1982). In that case, the challenged Illinois statute regulated corporations of other states, corporations doing little or no business in the state, and corporations lacking local shareholders. *Id.* at 645-46. The critical factor was that the regulated transactions between buyers and sellers outside Illinois were not sufficiently Illinois's affair to justify so much interference. *Id.* at 646. (This was the largest point of differentiation with *CTS Corp. v. Dynamics Corp. of America*, 481 U.S. at 93, upholding an Indiana takeover statute that was confined to corporations that were chartered in the state, had a large number of local shareholders, and were principally based or had major operations there.)

In sum, an approach to dormant Commerce Clause challenges based on protectionism furthers several compelling policies: The approach prevents states from engaging in overtly hostile acts against their sister states, thus provoking retaliation by competitor states. *Oklahoma Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179-80 (1995). Striking down protectionist legislation protects weaker states from acts by bigger, stronger states offering benefits to their own citizens at the expense of Americans outside their state borders. Moreover, a rule based on anti-protectionism serves the virtues of simplicity and certainty. *See Economic Un[illegible]*, 63 N.Y.U. L. Rev. at 113.

B. Maine Rx Is Protectionist Because Its Manipulation of Drug Prices for the Economic Advantage of Maine's Drug Consumers Causes Significant Impacts on Interstate Commerce

The protectionist nature of Maine Rx is demonstrated by its impact on Maine residents versus non-Maine residents. The Court should ask: "What is the potential impact on the rest of the American common market?" A manufacturer may offer special pricing in a limited number of states. But there is a real question as to how much a manufacturer could absorb if it is expected to sharply cut prices for residents of many states. Palumbo, Francis B., *The Role of the State As a Drug Purchaser*, 56 Food Drug L. J. 267, 271-72 (2001) (*Role of the State*). So while the facts of this case involve the relatively small Maine market, the Court should consider what would happen if California were to adopt a "California Rx" program.[4] Or if California joined with some other populous states to form a "Big Multi-State Rx" program. This is not outside the realm of possibility. For example, Maine Rx is not Maine's first attempt to obtain lower drug prices for its residents. In 2000, a coalition of Maine, Vermont, and New Hampshire solicited bids from pharmacy benefit manager organizations to run all three states' drug programs. The three states, which collectively have programs with over one million enrollees and one billion dollars in annual drug expenditures, sought to capitalize on their combined market share power by negotiating discounts without limitations. In any of these scenarios, the price cuts for residents within states with these programs would likely increase prices charged to customers in other states. *See, e.g.* General Accounting Office (GAO), Report to Congressional Requesters, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes*,

[4] In 2000, Maine had 1.27 million residents and California had 33.87 million residents. U.S. Census (2000) (http://quickfacts.census.gov) (visited Sept. 10, 2002).

GAO/HEHS-00-118 (2000) (a study of whether Federal Supply Schedule (FSS) prices should be extended to other programs concluded that prices paid by others would have to rise). The larger the group that would be newly entitled to receive a governmentally mandated price, the greater the incentive for drug manufacturers to raise that price for other purchasers. *Id.* So the states, in providing "coverage" for noninsured residents, may indeed be passing on the bill to other citizens in the form of increased premiums or decreased access in their private or employer-based health programs, as these programs may reduce coverage if the state steps in. *Role of the State*, 56 Food Drug L. J. at 272.

Two aspects of Maine Rx demonstrate the statute's protectionist nature. First is the provision forbidding companies from altering their distribution channels. Me. Rev. Stat. tit. 22. § 2697(2)(D). No drug manufacturers are located in Maine, and only one distributor resides there. As the district court correctly noted, the Act's purpose and effect is to lower the revenues received by these out-of-state manufacturers on drugs to be sold in Maine. *See Pharmaceutical Research and Manufacturers of America v. Commissioner*, 2000 U.S. Dist. LEXIS 17363, at *15 (D. Me. Oct. 26, 2000) (observing that the practical effect of the Act is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that are destined for Maine). No valid argument can be made that the Act, in its intent or practical effect, does not reach transactions between manufacturers and distributors. Pancoast, Abigail B., Comment, *A Test Case for Re-evaluation of the Dormant Commerce Clause: The Maine Rx Program*, 4 U. Pa. J. Const. L. 184, 199 (2001) (*Test Case*).

Maine correctly foresaw that leaving the state would otherwise be the reasoned response of the companies. In a boycotting effort, three prescription companies decided not to ship their medicines directly to Maine, using out-of-state wholesalers to supply non-Medicare recipients in the state.

Barrington, Conrad J., Note and Comment, *Pharmaceutical Research and Manufacturers of America v. Concannon and Maine's Prescription Drug Rebate Statute: A Twenty-First Century Solution to the Medicaid Crisis*, 23 Whittier L. Rev. 1127, 1132 (2002) (AstraZeneca, Bristol-Myers Squibb, and Smith-Kline Beecham). These companies' quick departure from the market vividly demonstrates the adverse incentives created by Maine Rx. This Court has held that "strong incentives," in lieu of direct regulation, are sufficient to implicate the dormant Commerce Clause. *Camps Newfound/Owatonna*, 520 U.S. at 578.

Second, when Maine requires pharmaceutical companies to offer discounted drug prices to Maine residents, the companies can be expected to recoup their losses by increasing prices paid by other people beyond Maine's borders. The GAO addressed this very issue in a 2000 study of whether FSS prices should be extended to other programs. The GAO concluded that prices paid by others would have to rise. GAO, Report to Congressional Requesters, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes*, GAO/HEHS-00-118. So Maine, by providing "coverage" for noninsured residents, may be passing on the bill to other citizens in the form of increased premiums or decreased access in their private or employer-based health programs. *See Role of the State*, 56 Food Drug L.J. at 271. Maine Rx sets the goal of "negotiations" between the manufacturers and the state to be FSS prices, which are the best prices obtained by any private purchaser. A private health plan cannot possibly negotiate a better price from a drug manufacturer. Then, Maine Rx Program participants are not subject to formularies, unlike the beneficiaries of many health plans that negotiate discounts from drug

manufacturers.[5] Uninsured and insured residents alike may all enroll in the Maine Rx Program and rely on private purchasers in other states to negotiate best-price discounts. In this scenario, purchasers in other states will have to pay more because drug manufacturers will be less inclined to give competitive discounts when they have to give the same discounts to the entire state of Maine. Stambaugh, Christopher R., Note, *State Price Control Laws Are the Wrong Prescription for the Problem of Unaffordable Drugs*, 12 Fordham Intell. Prop. Media & Ent. L.J. 897, 924 (2002) (*Wrong Prescription*).

The State can be expected to respond to this argument by asserting that the manufacturers *voluntarily* choose to provide rebates to Maine Rx participants. But Maine did not intend these agreements to be voluntary—in deciding to subject uncooperative manufacturers to the prior authorization requirement, the state had obviously determined that a voluntary program would not be sufficiently effective. The court below accepted the state's argument in this regard, holding that Maine Rx "merely says that the Commissioner of the Maine Department of Human Services shall use 'best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program . . . .'" *PhRMA*, 249 F.3d at 82 (citing Me. Rev. Stat. tit. 22, § 2681(4)(B)).

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[5] Although Maine Rx describes the State's role as a Pharmacy Benefit Manager (PBM), Me. Rev. Stat. tit. 22, § 2681(1), real PBMs use formularies to help control drug costs by (1) encouraging the use of formulary drugs through compliance programs that inform physicians and enrollees about which drugs are on the formularies; (2) limiting the number of drugs a plan will cover; or (3) developing financial incentives to encourage the use of formulary products. GAO Letter Report to the Honorable Ron Wyden, House of Representatives, *Pharmacy Benefit Managers: Early Results on Ventures with Drug Manufacturers*, GAO/HEHS-96-45 (1995). Maine Rx does not use formularies.

Thus the First Circuit held that the program was voluntary and the manufacturers could withdraw at any time. *Id.*

This holding represents willful blindness. The statute says manufacturers "shall" provide rebates (Me. Rev. Stat. tit. 22, § 2681(3)) and the very nature of the program demands manufacturers' compliance. First, the program contained the unconstitutional "anti-profiteering" sections, threatening treble compensatory damages, punitive damages, and civil penalties up to $100,000 if a company demanded terms the state determined to be "unreasonable" or if a manufacturer alters its business practices to avoid Maine's new law. Me. Rev. Stat. tit. 22, § 2697.[6] Second, Maine Rx imposes the prior authorization requirement on nonparticipants. Me. Rev. Stat. tit. 22, § 2681(7). Prior authorization means that a state bureaucrat has to approve a medication a doctor chooses for his or her patients. It slows down the dispensing procedure so much that instead of waiting for approval, doctors and patients are likely to seek alternative therapies. *Wrong Prescription*, 12 Fordham Intell. Prop. Med. & Ent. L. J. at 921. As a consequence, market shares of drugs that require prior authorization decline significantly. *Pharmaceutical Research and Manufacturers of America v. Medows*, 184 F. Supp. 2d 1186, 1192 (N.D. Fla. 2001) (naming drugs taken off a preferred drug list and requiring prior authorization: market share of Imitrex fell from 60% to 6%; the market share of Prilosec fell from 38% to 4%, and the market share of Allegra fell from 17% to 1%). The two provisions combined can only be construed as a requirement. *Test Case*, 4 U. Pa. J. Const. L. at 196.

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[6] The district court declared these provisions unconstitutional and the state did not appeal that ruling. They remain relevant to the inquiry before this Court, however, as they demonstrate that Maine never anticipated that manufacturers would voluntarily comply with the "negotiated" rebates.

This Court has expressly held that a state law using the state's leverage in one market where it does participate to achieve a separate regulatory purpose is subject to the dormant Commerce Clause as a state regulation and is not market participation. *South-Central Timber Development, Inc. v. Wunnicke*, 467 U.S. 82, 96-98 (1984) (holding that Alaska's statute limiting buyers of its timber to those who agreed to process the purchased timber in Alaska to be subject to the dormant Commerce Clause). *Test Case*, 4 U. Pa. J. Const. L. at 198. The court below recognized that Maine is not acting as a typical market participant as it neither buys nor sells pharmaceuticals (*PhRMA*, 249 F.3d at 80), but it erred by its failure to acknowledge the regulatory sanctions imposed by the program. Thus, Maine Rx fails dormant Commerce Clause analysis because it regulates extraterritorial economic transactions by imposing either a rebate agreement or a prior authorization requirement on drugs that are part of an out-of-state sale between out-of-state manufacturers who do not grant rebates, and out-of-state wholesalers and distributors. *See Test Case*, 4 U. Pa. J. Const. L. at 198.

As shown above, Maine Rx is likely to harm non-Maine drug consumers because pharmaceutical companies will seek to recoup the discounts they are required to offer to Maine residents by selling drugs outside the state at higher prices. As additional, and more populous, states replicate Maine's statutory scheme, the impact on consumers in those states without an "Rx" statute becomes more severe, causing a significant impact on interstate commerce as a whole. This protectionist policy should be held to be a violation of the dormant Commerce Clause.

II

MAINE RX DAMAGES THE AMERICAN COMMON MARKET

For private enterprise to flourish, a federal system must "prevent[] the lower governments from using their regulatory authority to erect trade barriers against the goods and services from other political units." Weingast, Barry R., *The Economic Role of Political Institutions: Market-Preserving Federalism and Economic Development*, 11 J.L. Econ. & Org. 1, 4 (1995) (*Market-Preserving Federalism*). The creation and preservation of a national common market is a central feature of "market-preserving federalism"—federalism that fosters economic growth by limiting the encroachment of a country's political system upon its markets. *Id.* at 3-4; *Preserving the American Common Market*, 7 S. Ct. Econ. Rev. at 235.

A. By Reinvesting Profits into Research and Development, American Pharmaceutical Companies Lead the World in the Creation of Life-Saving and Life-Enhancing Drugs

The American common market has created the most successful pharmaceutical industry in the world. Among the world's top 15 companies in the innovative drug industry in 1991, 8 were based in the United States. GAO, Report to the Chairman, Special Committee on Aging, U.S. Senate, *Prescription Drugs: Spending Controls in Four European Countries*, GAO/HEHS-94-30 (1994) (*Prescription Drugs*). United States-based pharmaceutical firms developed over 40 percent of the new major global drugs discovered between 1970 and 1992. *Id.* Success in this case is measured not only by the number of dollars in revenue, but by the number of lives saved and enhanced. American pharmaceutical companies generate more new and improved drugs than any other country. The reason can be traced to investment in R&D. Countries with higher drug prices tend to be associated with more pharmaceutical R&D and many new drugs. Conversely, in low-

price countries like Spain and Australia, R&D spending is low and very few new drugs are developed. *Prescription Drugs*, GAO/HEHS-94-30, at ch. 3:2.2. United States companies invest in the drawn-out development of new drugs because (1) they look forward to recovering their investment if the drug makes it through the gauntlet to be certified by the Food and Drug Administration (a process estimated to take 12 years with an average cost of $194 million (1990 dollars, net of various tax breaks) Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks, and Rewards*, OTA-H-522 at 1 (1993) (*Costs, Risks and Rewards*)); and (2) they enjoy national patent protection for the first few years the drug is on the market.

Pharmaceutical R&D is risky and expensive. Grabowski, Henry, *The Impact of the Clinton Health Care Reform Plan: Health Reform and Pharmaceutical Innovation*, 24 Seton Hall L. Rev. 1221, 1234-40 (1994) (*Pharmaceutical Innovation*); *see also* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 2-3 (July, 1998) (*Increased Competition*). Drug developers invest heavily in R&D because they expect to profit from it. *Increased Competition* at 2 ("Producers of innovator drugs invest heavily in research and development (R&D), hoping to recoup that investment in profits from future sales while a drug is under patent and they have a monopoly on its manufacture."); *see also Pharmaceutical Innovation*, 24 Seton Hall L. Rev. at 1258 ("A firm undertaking long-term risky R&D programs on new drugs must make an investment decision on the bases of expectations."). Higher drug prices strengthen the incentive for R&D. The GAO estimated that a 1% decline in drug prices leads to a 0.68% decline in R&D spending. This is consistent with previous economic analyses of the pharmaceutical industry, in which other measures of the incentive for R&D—for example, firms' profit rates and market shares—were positively related to R&D. GAO, *Prescription*

Drugs, GAO/HEHS-94-30, at ch. 3:3 (citing Comanor, William S., *The Political Economy of the Pharmaceutical Industry*, 24 Journal of Economic Literature 1178 (1986)); U.S. International Trade Commission, Report to the Committee on Finance, U.S. Senate, *Global Competitiveness of U.S. Advanced-Technology Manufacturing Industries: Pharmaceuticals*, US ITC Pub. 2437 (1991).

The dramatic increase in real revenues to new drugs throughout the 1980s sent signals to the industry that more investment would be rewarded handsomely. The industry responded by increasing its commitment to investment in R&D. *Costs, Risks and Rewards*, OTA-H-522 at 104; *Wrong Prescription*, 12 Fordham Intell. Prop. Media & Ent. L.J. at 906. A few "blockbuster" drugs have generated incredible profits for their patent owners. Stanton, Jerry, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 Conn. J. Int'l L. 149, 169 (2000) (*Lesson*) (citing Grabowski, Henry, *Health Reform and Pharmaceutical Innovation* 13-25 (1994)). But laws that would limit the amount that drug developers can make from future blockbuster drugs would drastically reduce the expected profits for drug developers, and therefore would drastically reduce investment in pharmaceutical R&D. *Id.*[7]

R&D innovation further depends on patent protection because competing drug manufacturers would undersell the developers before the developers recouped their investment in R&D and made a profit from it. "Without patents, many new drugs could be easily and quickly duplicated by other

[7] While other options for funding R&D exist, such as debt financing and equity financing, these options are not feasible given the extremely high cost—if not outright impossibility—of gathering impartial information to provide to investors. This is why most major pharmaceutical companies finance their R&D through retained earnings. *Prescription Drugs*, GAO/HEHS-94-30 at App. V:2.2 n.8.

manufacturers, preventing the innovator firm from obtaining enough reward to justify its investment." *Increased Competition* at 3. With patent protection, a drug developer looks to demand a price high enough to recoup the costs of R&D and make a profit. *Id.* Patents do not guarantee a profit for drug developers, but they make it a possibility by allowing drug developers to demand higher prices than they could without patent protection. *Wrong Prescription*, 12 Fordham Intell. Prop. Media & Ent. L.J. at 903-04.

R&D clearly emerges as the primary cause of American dominance in pharmaceutical innovation. Moreover, by advancing the state of scientific and medical knowledge, R&D benefits society above and beyond revenue received by direct sales of the resulting drugs. *Prescription Drugs*, GAO/HEHS-94-30 at Appendix V:1. The national commitment to maintaining America's standing as the leader in pharmaceutical development must not be undermined by this Court's approval of a states' efforts to reduce drug prices for their populations.[8]

B. Pharmaceutical Price Controls Have a Direct, Adverse Impact on Research, Development, and Innovation

Possibly the biggest threat to pharmaceutical companies who do business in Maine is the prospect of price controls if the "negotiations" on rebates do not favor the state in the amount the state deems appropriate. Me. Rev. Stat. tit. 22, §§ 2691, 2693(1). Price controls enacted by even one state can damage the American common market in pharmaceuticals. But price controls are unlikely to remain so contained. Protectionist politics invite retaliatory protectionism by other states, until

[8] Congress may be willing to risk some trade-offs between price reduction and R&D. *See, e.g.*, H.R. 5186 (Drug Importation Act of 2002) (permitting reimportation of drugs from Canada at possibly lower prices). The wisdom of such a choice is not before this Court, and, at any rate, does not implicate the Commerce Clause.

protectionists dominate in all states. *Economic Union*, 63 N.Y.U. L. Rev. at 77. Specific to this case, twenty-three states already have considered enacting "clones" of the Maine Rx Program legislation. Woellert, Lorraine, *The States Step into the Breach*, Bus. Week, Aug. 6, 2001, at 33. If this Court's decision invites these other states to follow Maine's example, lessons learned by other nations' imposition of price controls suggest that American patients will surely suffer.

Canada, the United Kingdom, France, Japan, and other countries have implemented pharmaceutical price controls for many years. *Lesson*, 16 Conn. J. Int'l L. at 160-64; *see also* Danzon, Patricia M., *Pharmaceutical Price Regulation* 15-29 (Ann Petty ed., 1997). The forms of their price regulations vary, but they all stifle competition and discourage innovation in the pharmaceutical industry. *Lesson*, 16 Conn. J. Int'l L. at 165-71; *Pharmaceutical Price Regulation* at 58-64. In many of these countries, purchasing power is lower than in the United States, and in most of these countries, the level of research and development of pharmaceuticals is not as extensive as in the United States. *Role of the State*, 56 Food Drug L.J. at 269 (citing Kolassa, Eugene M., *Elements of Pharmaceutical Pricing* 108-09 (Haworth Press 1997).

A study by Wharton economist Patricia Danzon used empirical evidence to thoroughly examine the effects of each of these countries' price regulations on incentives for pharmaceutical innovation, production efficiency, goals of controlling total drug expenditures, and quality of patient care. *Pharmaceutical Price Regulation* at 3-4. The evidence showed that no country with price controls has had innovative success in the pharmaceutical industry that matches that of the United States. *Id.* at 58-63. In fact, Danzon found "a rough negative correlation between the stringency of a country's price controls

and the innovative success of its domestic pharmaceutical industry." *Id.* at 63.

France, Germany, Sweden, and the United Kingdom have adopted price restraint mechanisms. Although they differ in their application, these countries' measures did lower prescription drug prices. However, these policies created a conflict between the interest in containing prescription drug costs and the economic burden subsequently borne by the domestic pharmaceutical industry, particularly on pharmaceutical R&D. This tension transcended the specifics of each country's pharmaceutical policies. *Prescription Drugs*, GAO/HEHS-94-30, at ch. 3.1. Based on its analysis of the four counties noted above, the GAO found that a reduction in prescription drug prices can be expected to reduce companies' spending on pharmaceutical R&D because firms will have less incentive to invest in R&D when they expect to receive lower prices for their products. *Id.*

Price controls in other countries allow them to "free-ride" on American manufacturers who invest in innovation. *Pharmaceutical Price Regulation* at 93. Controlled prices that cover only slightly more than the marginal cost of manufacturing a drug discourage pharmaceutical innovation by making R&D a less profitable investment. *Wrong Prescription*, 12 Fordham Intell. Prop. Media & Ent. L.J. at 913. Recognizing this cause and effect, the United States has pressured other countries to relax their regulations on drug prices. Harrison, Christopher Scott, Comment, *Protection of Pharmaceuticals As Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91*, 26 N.C. J. Int'l L. & Com. Reg. 457, 457-62 (2001) (discussing how the United States

pressured Canada to abandon its compulsory licensing law for patented pharmaceuticals).

From a public policy perspective, little can be gained from the imposition of price controls over new drugs and a great deal lost. Even if the government eliminated all profits from future drugs coming into the market, the prospective savings in terms of overall health care costs would be less than one percent of health care costs. *Wrong Prescription*, 12 Fordham Intell. Prop. Media & Ent. L.J. at 900. However, these actions would have precipitous effects on the incentives for research on innovative new medicines. Over the long term, patient welfare would be lower and total health care costs higher. *Pharmaceutical Innovation*, 24 Seton Hall L. Rev. at 1259.

Maine holds out the most feared consequence for pharmaceutical companies' failure to "negotiate" to the state's desired outcome: price controls. The certain adverse effect of price controls on America's premier pharmaceutical industry is a factor this Court should consider as it analyzes the impact of Maine Rx on the American common market.

CONCLUSION

Maine Rx would force pharmaceutical companies to provide drugs to Maine residents at lower prices than are available to the rest of the country. As a consequence, Americans not residing in Maine are likely to pay higher drug prices to make up the difference. Moreover, Maine's threatened price controls coerce cooperation in the Maine Rx statutory scheme. This is protectionist legislation that cannot be sanctioned under the dormant Commerce Clause.

The judgment of the First Circuit Court of Appeals should be reversed.

DATED: September, 2002.

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No. 01-188

IN THE
Supreme Court of the United States

Supreme Court, U.S.
FILED
SEP 20 2002
CLERK

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

JOINT APPENDIX

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September 20, 2002

PETITION FOR CERTIORARI FILED JULY 31, 2001
CERTIORARI GRANTED JUNE 28, 2002

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NOTICE

The following documents have been omitted in the printing of this Joint Appendix. They may be found in the Petitioners' Appendix to the 01-188 Petition For A Writ Of Certiorari at the following pages:

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MAINE DISTRICT COURT

1:2000cv00157

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, et al.,

Defendants.

DOCKET ENTRIES

DATE	NO.	PROCEEDINGS
8/10/00	1	COMPLAINT filed; FILING FEE $ 150 RECEIPT # 41094 (Service of Process Deadline 12/8/00) (hdj) [Entry date 08/11/00]
8/10/00	2	MOTION by PHARMACEUTICAL RESEA for Leave to File memo in excess of page limits (hdj) [Entry date 08/11/00]
8/10/00	3	MOTION with memorandum in support by PHARMACEUTICAL RESEA for Preliminary Injunction (hdj) [Entry date 08/11/00]
8/10/00	4	AFFIDAVIT of Russel A. Bantham (hdj) [Entry date 08/11/00]
8/10/00	5	AFFIDAVIT of Richard A. Feldman (hdj) [Entry date 08/11/00]
8/10/00	6	AFFIDAVIT of George Bilyk (hdj) [Entry date 08/11/00]

DATE	NO.	PROCEEDINGS
8/10/00	7	AFFIDAVIT of Thomas M. McPhillips (hdj) [Entry date 08/11/00]
8/10/00	8	AFFIDAVIT of Judith L. Tempel (hdj) [Entry date 08/11/00]
8/10/00	9	AFFIDAVIT of David Moules (hdj) [Entry date 08/11/00]
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8/11/00	—	CORPORATE DISCLOSURE STATEMENT per Local Rule 83.7 by PHARMACEUTICAL RESEA (hdj)
8/11/00	—	Pro Hac Vice Certificate for PHARMACEUTICAL RESEA by DANIEL M. PRICE, ALLEN S. RUGG (hdj)
8/11/00	—	ENDORSEMENT on Motion granting [2-1] motion for Leave to File memo in excess of page limits (/s/For the Court, Harriett D. Jefferson, Deputy Clerk) cc: cnsl (hdj)
8/16/00	—	RETURN of Service Executed as to HS, ME COMMN, ATTORNEY GENERAL, ME 8/11/00 Answer due on 8/31/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw)
8/23/00	—	MOTION during telephone conference by HS, ME COMMN, ATTORNEY GENERAL, ME to Extend Time to file answer and response to preliminary injunction motion (jgw)

DATE	NO.	PROCEEDINGS
8/23/00	11	REPORT of Conference of Counsel granting in part [0-0] oral motion to Extend Time to file answer and response to preliminary injunction motion, reset Answer deadline to 9/11/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN, Response to Motion reset to 9/11/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN for [3-1] motion for Preliminary Injunction (signed by MAG. JUDGE MARGARET J. KRAVCHUK) cc: cnsl (jgw) PORTLD STNDRD
9/11/00	12	MOTION by HS, ME COMMN, ATTORNEY GENERAL, ME for Leave to File response in excess of page limits (jgw)
9/11/00	13	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [3-1] motion for Preliminary Injunction ; Reply to Response due 9/21/00 for PHARMACEUTICAL RESEA (jgw)
9/11/00	14	AFFIDAVIT of Kevin Concannon (jgw)
9/11/00	15	AFFIDAVIT of Timothy S. Clifford, M.D. (jgw)
9/11/00	16	AFFIDAVIT of Buritt Richardson, Jr., M.D. (jgw)
9/11/00	17	ANSWER to Complaint by HS, ME COMMN, ATTORNEY GENERAL, ME (jgw)

DATE	NO.	PROCEEDINGS
9/12/00	—	ENDORSEMENT on Motion granting [12-1] motion for Leave to File response in excess of page limits (signed by Walentine, DC for JUDGE D. B. HORNBY) cc: cnsl (jgw)
9/20/00	18	Letter MOTION by HS, ME COMMN, ATTORNEY GENERAL, ME for Order granting protection from hearing or o/a from 9/27 to 10/13 (err)
9/20/00	—	Motion(s) taken under advisement: [18-1] motion for Order granting protection from hearing or o/a from 9/27 to 10/13 under advisement (err)
9/21/00	—	Pro Hac Vice Certificate for PHARMACEUTICAL RESEA by KATHLEEN M. SULLIVAN (jgw)
9/21/00	19	MOTION by PHARMACEUTICAL RESEA for Leave to File reply brief in excess of page limits (jgw)
9/21/00	20	REPLY by PHARMACEUTICAL RESEA to response to [3-1] motion for Preliminary Injunction (jgw)
9/21/00	—	ENDORSEMENT on Motion granting [19-1] motion for Leave to File reply brief in excess of page limits (signed by Walentine, DC for JUDGE D. B. HORNBY) cc: cnsl (jgw)
9/21/00	21	MOTION by PHARMACEUTICAL RESEA for Hearing on [3-1] motion for Preliminary Injunction (jgw)

DATE	NO.	PROCEEDINGS
9/21/00	—	Motion(s) taken under advisement: [21-1] motion for Hearing on [3-1] motion for Preliminary Injunction under advisement (jgw)
9/26/00	22	Letter RESPONSE by PHARMACEUTICAL RESEA to [18-1] motion for Order granting protection from hearing or o/a from 9/27 to 10/13 ; Reply to Response due 10/6/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw) [Entry date 09/27/00] PORTLD STNDRD
9/28/00	—	ENDORSEMENT on Motion granting [21-1] motion for Hearing on [3-1] motion for Preliminary Injunction, granting [18-1] motion for Order granting protection from hearing or o/a from 9/27 to 10/13, Motion Hearing Set Re: [3-1] motion for Preliminary Injunction set for 9:00 10/19/00 (signed by Deputy Clerk, Marie Cross for JUDGE D. B. HORNBY) cc: cnsl (mmc)
10/3/00	23	ORDER (re: the Hearing set for 10/19/00 on the Motion for Preliminary Injunction), set Telephone Conference for 3:30 10/17/00 (re: final hearing on the merits, factual disputes, etc.) (signed by JUDGE D. B. HORNBY) cc: cnsl (mmc)
10/17/00	—	Tele-conference re: held. The Court has determined that the parties will proceed on the Preliminary Injunction Argument only on 10/19/00. (Court Reporter: Pauline Terry) before JUDGE D. B. HORNBY (mmc) [Entry date 10/19/00]

DATE	NO.	PROCEEDINGS
10/19/00	—	Motion(s) taken under advisement: [3-1] motion for Preliminary Injunction under advisement (mmc)
10/19/00	—	MOTION Hearing held re: [3-1] motion for Preliminary Injunction before JUDGE D. B. HORNBY. Any further filings shall be filed by 10/23/00. (Court Reporter: Pauline Terry) (mmc)
10/20/00	24	TRANSCRIPT filed of HEARING ON #3, MOTION FOR PRELIMINARY INJUNCTION for dates of: 10/19/2000, held before Judge D. BROCK HORNBY (Court Reporter: PAULINE TERRY) (dw)
10/23/00	25	MOTION (no objection) by MAINE COUNCIL OF SEN, VIOLA QUIRION for Leave to File Brief of amicus curiae (mmc)
10/23/00	26	AFFIDAVIT of John Moran (mmc)
10/23/00	27	AFFIDAVIT of Viola Quirion (mmc)
10/23/00	28	BRIEF filed by MAINE COUNCIL OF SEN, VIOLA QUIRION (mmc)
10/23/00	29	BRIEF filed by HS, ME COMMN, ATTORNEY GENERAL, ME (mmc)
10/23/00	30	BRIEF filed by PHARMACEUTICAL RESEA (mmc) PORTLD STNDRD
10/26/00	31	ORDER granting by agreement [25-1] motion for Leave to File Brief of amicus curiae, granting [3-1] motion for Preliminary Injunction. The Commisioner is here by preliminarily enjoined from penalizing manufacturers, by placing their drugs on

DATE	NO.	PROCEEDINGS
		prior listing status, for refusing to negotiate or to pay a rebate to Maine's RX program. The Attorney General is hereby preliminarily enjoined from seeking to enforce the illegal profiteering portion of the statute against transactions that occur outside the State of Maine, even of the presciption drugs eventually end up and are ultimately purchased in Maine. So Ordered. (signed by JUDGE D. B. HORNBY) cc: cnsl (mmc)
11/9/00	32	NOTICE OF INTERLOCUTORY APPEAL of [31-1] order by HS, ME COMMN, ATTORNEY GENERAL, ME FILING FEE $ 105 RECEIPT # 41921 (bfa)
11/9/00	—	CERTIFICATE of Clerk (Form 83) Org docs #: 1-32 (bfa)
11/9/00	—	Certified and transmitted record on appeal to U.S. Court of Appeals: [32-1] interlocutory appeal by ATTORNEY GENERAL, ME, HS, ME COMMN (bfa)
11/13/00	33	MOTION with memorandum in support by VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE to Intervene ; Response to Motion due 12/1/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (mjl)
11/13/00	34	AFFIDAVIT of Viola Quirion (mjl)
11/13/00	35	AFFIDAVIT of Michelle Campbell (mjl)

DATE	NO.	PROCEEDINGS
11/13/00	36	AFFIDAVIT of John Moran (mjl)
11/13/00	37	AFFIDAVIT of Richard J. Donahue, M.D. (mjl)
11/22/00	38	MOTION with memorandum in support by VIOLA QUIRION, MICHELLE CAMPBELL, RICHARD DONAHUE to Extend Time to file a Notice of Appeal (mnm)
12/1/00	39	RESPONSE by PHARMACEUTICAL RESEA to [33-1] motion to Intervene ; Reply to Response due 12/11/00 for RICHARD DONAHUE, for MAINE COUNCIL OF SEN, for MICHELLE CAMPBELL, for VIOLA QUIRION (mnm)
12/4/00	—	USCA Case Number Re: interlocutory appeal USCA NUMBER: 00-2446 (jgw)
12/4/00	40	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [33-1] motion to Intervene-(The defendants do not object to the motion to intervene filed by the Maine Council of Senior Citizens, et al. We will not be filing a memorandum in response to that motion.) (mnm) [Entry date 12/06/00] PORTLD STNDRD
12/11/00	41	REPLY by VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE to response to [33-1] motion to Intervene (dw)
12/11/00	—	Motion(s) taken under advisement: [33-1] motion to Intervene under advisement-(dw)

DATE	NO.	PROCEEDINGS
12/14/00	42	ORDER denying [33-1] motion to Intervene-For these reasons, the motion to intervene is Denied and the motion for extention of time to file a notice of appeal is Denied because I have denied the motion to intervene. No action is necessary on the motion to alter or amend judgment and to dismiss Count V of the plaintiffs complaint (signed by JUDGE D. B. HORNBY) cc: cnsl (mnm) [Entry date 12/15/00]
12/14/00	—	ENDORSEMENT on Motion denying [38-1] motion to Extend Time to file a Notice of Appeal-see order #42 dated 12/14/00-The motion to intervene is DENIED and the motion for extension of time to file a notice of appeal is DENIED because I have denied the motion to intervene. No action is necessary on the motion to alter or amend judgment and to dismiss Count V of the plaintiff's Complaint (signed by JUDGE D. B. HORNBY) cc: cnsl (mnm) [Entry date 12/19/00]
4/9/01	43	MOTION to Intervene by EDWIN D SCHINDLER on behalf of plaintiff ; Response to Motion due 4/30/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw)
4/27/01	44	RESPONSE by PHARMACEUTICAL RESEA to [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff ; Reply to Response due 5/8/01 for EDWIN D SCHINDLER (mlh)

DATE	NO.	PROCEEDINGS
4/30/01	45	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff ; Reply to Response due 5/11/01 for EDWIN D SCHINDLER (mmc) [Entry date 05/01/01]
5/7/01	47	MOTION by EDWIN D SCHINDLER for Clarification of Page Limit Set by Local Rule 7(c) and, if necessary for Leave to File reply in excess of page limit; Response to Motion due 5729/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (mlh)
5/7/01	48	REPLY by EDWIN D SCHINDLER to response to [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff (mlh)
5/7/01	—	Motion(s) taken under advisement: [47-1] motion for Clarification of Page Limit Set by Local Rule 7(c) under advisement, [47-2] motion for Leave to File reply in excess of page limit under advisement, [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff under advisement (mlh) PORTLD STNDRD
5/7/01	46	SUPPLEMENTAL FILING by EDWIN SCHINDLER in Support of His Pending Motion for Intervention (mlh) [Entry date 05/08/01]

DATE	NO.	PROCEEDINGS
5/18/01	49	OPINION of USCA re: [32-1] interlocutory appeal Decision: District Court is reversed and the temporary injunction is vacated. (Mandate Deadline set for 6/18/01) (ckb) [Entry date 05/21/01]
5/21/01	50	MOTION by EDWIN D SCHINDLER for Expedited Order on pending motion to intervene ; Response to Motion due 6/11/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw)
6/8/01	51	ORDER ON EDWIN D. SCHINDLER'S MOTION TO INTERVENE denying [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff (signed by JUDGE D. B. HORNBY) cc: cnsl (dw)
6/8/01	—	ENDORSEMENT on Motion terminating [47-1] motion for Clarification of Page Limit Set by Local Rule 7(c), granting [47-2] motion for Leave to File reply in excess of page limit (signed by JUDGE D. B. HORNBY) cc: cnsl (mmc) [Entry date 06/11/01]
6/8/01	—	ENDORSEMENT (see order issued on 6/8/01 denying motion to intervene) on Motion granting [50-1] motion for Expedited Order on pending motion to intervene (signed by JUDGE D. B. HORNBY) cc: cnsl (mmc) [Entry date 06/12/01]
6/12/01	52	MOTION by EDWIN D SCHINDLER for Reconsideration of [51-1] order denying #43 Motion to Intervene ; Response to

DATE	NO.	PROCEEDINGS
		Motion due 7/3/01 for RICHARD DONAHUE, for MAINE COUNCIL OF SEN, for MICHELLE CAMPBELL, for VIOLA QUIRION, for VIOLA QUIRION, for MAINE COUNCIL OF SEN, for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (err)
6/20/01	53	MEMORANDUM by EDWIN D SCHINDLER in support of [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (bld)
6/25/01	54	RESPONSE to by PHARMACEUTICAL RESEA to supplemental memo in support of [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene ; Reply to Response due 7/6/01 for EDWIN D SCHINDLER (jgw) [Entry date 06/29/01]
6/29/01	55	REPLY by EDWIN D SCHINDLER to response to [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (jgw)
6/29/01	56	RESPONSE by ATTORNEY GENERAL, ME to [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene ; Reply to Response due 7/10/01 for EDWIN D SCHINDLER (dw) PORTLD STNDRD

DATE	NO.	PROCEEDINGS
7/2/01	57	REPLY by EDWIN D SCHINDLER to response (#56) to [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (jgw) [Entry date 07/05/01]
7/5/01	—	Motion(s) taken under advisement: [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene under advisement (jgw)
7/5/01	58	NOTICE OF INTERLOCUTORY APPEAL of [51-1] order denying mtn to intervene by EDWIN D SCHINDLER FILING FEE $ 105.00 RECEIPT # 43186 (jgw)
7/6/01	59	Amended NOTICE OF INTERLOCUTORY APPEAL of [51-1] order denying mtn to intervene by EDWIN D SCHINDLER FILING FEE $ 105.00 RECEIPT # 43190 (jgw)
7/10/01	—	ENDORSEMENT on Motion denying [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (signed by JUDGE D. B. HORNBY) cc: cnsl (jgw)
7/10/01	—	COPIES of Notice of Appeal sent to counsel. Parties: PHARMACEUTICAL RESEA, HS, ME COMMN, ATTORNEY GENERAL, ME, MAINE COUNCIL OF SEN, VIOLA QUIRION, VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE, EDWIN D SCHINDLER (jgw)

DATE	NO.	PROCEEDINGS
7/10/01	—	CLERK'S SUPPLEMENTAL CERTIFICATE (re: [59-1] interlocutory appeal, [58-1] interlocutory appeal) ; 1ST supplemental certificate; Orig. documents numbered: 33-59 (jgw)
7/10/01	—	Transmitted supplemental record on appeal: [59-1] interlocutory appeal by EDWIN D SCHINDLER, [58-1] interlocutory appeal by EDWIN D SCHINDLER (jgw)
7/11/01	—	Deadline updated as Order issued in USCA staying entry of Mandate; reset Mandate deadline to 8/10/01 (jgw)
7/16/01	—	USCA Case Number Re: [59-1] interlocutory appeal by EDWIN D SCHINDLER, [58-1] interlocutory appeal by EDWIN D SCHINDLER USCA NUMBER: 01-2006 (jgw)
7/17/01	60	SECOND AMENDED NOTICE OF INTERLOCUTORY APPEAL of [0-0] order ENDORSEMENT on Motion denying [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene, [51-1] order by EDWIN D SCHINDLER FILING FEE $ 105.00 RECEIPT # 43207 (jgw) [Edit date 07/20/01]
7/20/01	—	CLERK'S SUPPLEMENTAL CERTIFICATE (re: [60-1] interlocutory appeal) ; 2nd supplemental certificate; Orig. documents numbered: 60 (jgw)

DATE	NO.	PROCEEDINGS
7/20/01	—	Transmitted supplemental record on appeal: [60-1] interlocutory appeal by EDWIN D SCHINDLER (jgw) PORTLD STNDRD
7/20/01	—	COPIES of 2nd amended Notice of Appeal sent to counsel. Parties: PHARMACEUTICAL RESEA, HS, ME COMMN, ATTORNEY GENERAL, ME, MAINE COUNCIL OF SEN, VIOLA QUIRION, VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE, EDWIN D SCHINDLER (jgw)
7/23/01	61	MOTION by EDWIN D SCHINDLER to Stay proceedings pending appeal of district court Order denying mtn to intervene ; Response to Motion due 8/13/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (jgw)
8/13/01	—	Deadline updated; reset Mandate deadline to 8/17/01 (err)
8/13/01	62	RESPONSE by PHARMACEUTICAL RESEA to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene ; Reply to Response due 8/24/01 for EDWIN D SCHINDLER (err)

DATE	NO.	PROCEEDINGS
8/13/01	63	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene ; Reply to Response due 8/24/01 for EDWIN D SCHINDLER (mmc) [Entry date 08/14/01]
8/16/01	64	REPLY by EDWIN D SCHINDLER to Dfts' response to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene (jgw)
8/16/01	65	REPLY by EDWIN D SCHINDLER to pltf's response to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene (jgw)
8/16/01	—	Motion(s) taken under advisement: [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene under advisement (jgw)
8/20/01	66	(NOTICE) MEMORANDUM by EDWIN D SCHINDLER in support of [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene (jgw)
8/20/01	—	ENDORSEMENT on Motion denying [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene "Denied. (There are no proceedings currently pending before this court.)" (signed by JUDGE D. B. HORNBY) cc: cnsl (mnm) [Entry date 08/21/01]

DATE	NO.	PROCEEDINGS
8/24/01	67	NOTICE OF INTERLOCUTORY APPEAL to the Federal Circuit Court of Appeals of [0-0] order ENDORSEMENT on Motion denying [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene, [51-1] order by EDWIN D SCHINDLER FILING FEE $ 105.00 RECEIPT # 43249 (jgw) PORTLD STNDRD
8/24/01	—	COPIES of Notice of Appeal sent to counsel. Parties: PHARMACEUTICAL RESEA, HS, ME COMMN, ATTORNEY GENERAL, ME, MAINE COUNCIL OF SEN, VIOLA QUIRION, VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE, EDWIN D SCHINDLER (jgw)
8/29/01	68	ORDER from U.S. Court of Appeals rescinding Order dated August 13, 2001 issuing mandate (jgw)
8/29/01	69	ORDER from U.S. Court of Appeals denying motion to stay mandate by amicus curiae Edwin R. [sic] Schindler (jgw)
9/4/01	—	U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT; Case Number Re: [67-1] interlocutory appeal by EDWIN D SCHINDLER USCA NUMBER: 01-1597 (jgw)
9/4/01	—	Deadline updated; reset Mandate deadline to 9/11/01 (err)

DATE	NO.	PROCEEDINGS
9/13/01	—	Deadline updated; reset Mandate deadline to 9/17/01 (bld)
9/18/01	—	Deadline updated; reset Mandate deadline to 10/1/01 (jgw)
9/19/01	70	MANDATE/JUDGMENT OF USCA (certified copy) dated 8/13/01 Re: [32-1] interlocutory appeal by ATTORNEY GENERAL, ME, HS, ME COMMN Decision: Judgment of USDC reversed and temporary injunction vacated (please refer to USCA Order #68 rescinding issuance of this mandate) (jgw) [Entry date 09/21/01]
10/9/01	71	MOTION by EDWIN D SCHINDLER to Intervene by EDWIN D SCHINDLER to appeal anticipated entry of final judgment against PhRMA ; Response to Motion due 10/30/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (jgw) [Entry date 10/10/01] [Edit date 10/10/01]
10/9/01	72	MOTION by EDWIN D SCHINDLER to Stay proceedings in USDC pending appeal in Federal Circuit ; Response to Motion due 10/30/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (jgw) [Entry date 10/10/01]

DATE	NO.	PROCEEDINGS
10/10/01	73	WITHDRAWAL of [71-1] motion to Intervene by EDWIN D SCHINDLER to appeal anticipated entry of final judgment against PhRMA, [72-1] motion to Stay proceedings in USDC pending appeal in Federal Circuit (jgw)
10/22/01	74	MANDATE/JUDGMENT OF Federal Circuit Court (certified copy) Re: [67-1] interlocutory appeal by EDWIN D SCHINDLER Decision: Maine dfts mtn to dismiss this appeal granted; Schindler's motions are moot; Schindler's petition for writ of mandamus is denied (jgw) [Edit date 10/22/01] PORTLD STNDRD
10/30/01	75	Interlocutory MANDATE/JUDGMENT OF USCA (certified copy) Re: [60-1] interlocutory appeal by EDWIN D SCHINDLER, [59-1] interlocutory appeal by EDWIN D SCHINDLER, [58-1] interlocutory appeal by EDWIN D SCHINDLER Decision: Appeal DISMISSED (err) [Entry date 10/31/01] [Edit date 10/31/01]
5/28/02	76	MOTION by PHARMACEUTICAL RESEA for Allen S. Rugg to Withdraw as Counsel (err)
5/29/02	—	ENDORSEMENT on Motion granting [76-1] motion for Allen S. Rugg to Withdraw as Counsel ("Granted. Other counsel have appeared.") (signed by MAG. JUDGE MARGARET J. KRAVCHUK) cc: cnsl (err)

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 00-2446

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff-Appellee,

v.

COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES; ATTORNEY GENERAL, ME
Defendants-Appellants.

DOCKET ENTRIES

DATE	PROCEEDINGS
11/22/00	CIVIL CASE docketed. Opening forms sent. Notice filed by Appellants Commissioner, and Attorney General, ME. Appearance form due 12/6/00. Docketing Statement due 12/6/00. [00-2446] (cmpa) [00-2446]
11/22/00	RECORD filed: 1 volume(s). Transcript of Hearing on Preliminary Injunction included. [516840-1] [00-2446] (cmpa) [00-2446]
11/29/00	TRANSCRIPT REPORT/ORDER filed by Appellants Commissioner and Attorney General, ME. Transcript is already on file in the Clerk's office. [00-2446] (cmpa) [00-2446]
11/29/00	BRIEFING SCHEDULE. Appellant's Brief due 1/8/01. Appendix due 1/8/01. Appellee's Brief due 2/7/01. Reply brief due 2/21/01. [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
11/30/00	MOTION filed by Appellant Commissioner of the Maine Department of Human Services and Attorney General, ME to expedite appeal. Certificate of service 11/28/00. [00-2446] (cmpa) [00-2446]
11/30/00	APPEARANCE filed by Kathleen M. Sullivan for Appellees Pharmaceutical Research Pharmaceutical and Manufacturers of America. [518686-1] [00-2446] (cmpa) [00-2446]
11/30/00	APPEARANCE filed by Andrew S. Hagler for Appellants Attorney General, ME, and Commissioner. [519912-1] [00-2446] (cmpa) [00-2446]
11/30/00	DOCKETING STATEMENT filed by Appellants Commissioner and Attorney General, ME. [00-2446] (cmpa) [00-2446]
12/4/00	DISCLOSURE STATEMENT on behalf of Appellee Pharmaceutical Resea filed. [00-2446] (cmpa) [00-2446]
12/4/00	APPEARANCE filed by Bruce C. Gerrity for Appellee Pharmaceutical Research. [519891-1] [00-2446] (cmpa) [00-2446]
12/4/00	APPEARANCE filed by Allen S. Rugg for Appellee Pharmaceutical Research. [519894-1] [00-2446] (cmpa) [00-2446]
12/4/00	APPEARANCE filed by John R. Brautigam for Appellants Attorney General, ME, and Commissioner. [519896-1] [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
12/5/00	RESPONSE filed by Appellee Pharmaceutical Research to motion to expedite appeal [518606-1]. Parties agree on briefing schedule. Certificate of service dated 12/5/00 [519953-1] [00-2446] (cmpa) [00-2446]
12/5/00	APPEARANCE filed by Daniel M. Price for Appellee Pharmaceutical Research. [519957-1] [00-2446] (cmpa) [00-2446]
12/11/00	ORDER filed. Appellants' motion for an expedited appeal is granted to the extent set out in the parties' agreed upon briefing schedule. That is, appellants' brief will be due by January 8, 2001, appellee's brief shall be filed within thirty days of the date of the filing of appellants' brief, and appellants' reply brief will be due within fourteen days of the filing of appellee's brief. If the briefs are filed according to this schedule, then oral argument will be scheduled for the court's March 2001 sitting. (ciny) [00-2446]
12/11/00	BRIEFING SCHEDULE. Appellant's Brief due 1/8/01. Appendix due 1/8/01. Appellee's Brief due 2/7/01. Reply brief due 2/21/01. [00-2446] (ciny) [00-2446]
12/11/00	LETTER filed by Thomas C. Bradley on behalf of the Maine Citizen Leadership Fund informing the court that a motion to intervene was filed on their behalf in the district court. [00-2446] (kati) [00-2446]

DATE	PROCEEDINGS
1/9/01	BRIEF filed by Appellant Attorney General, ME and Appellant Kevin Concannon. Pages: 60. Copies: 10, delivered by mail. Certificate of service date 01/08/01. [526780-1] Appellee brief due 2/8/01. [00-2446] (karn) [00-2446]
1/9/01	ELECTRONIC DOCUMENT filed by Appellant Commissioner and Appellant Attorney General, ME. [00-2446] (karn) [00-2446]
1/9/01	APPENDIX filed by Appellant Commissioner and Appellant Attorney General, ME. Copies: 5. Volumes: 1. Delivered by mail, filed. Certificate of service date 1/8/01. [526805-1] [00-2446] (karn) [00-2446]
1/17/01	APPEARANCE filed by Thomas Charles Bradley for Amicus Curiae Richard Donahue, Amicus Curiae Michelle Campbell. [529329-1] [00-2446] (mlyn) [00-2446]
1/17/01	APPEARANCE filed by Arn H. Pearson for Amicus Curiae Richard Donahue, Amicus Curiae Michelle Campbell, Amicus Curiae Viola Quirion, Amicus Curiae Maine Council. [529333-1] [00-2446] (mlyn) [00-2446]
1/17/01	MOTION filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue to file appendix. Certificate of service dated 1/16/01. [00-2446] (mlyn) [00-2446]
1/18/01	PARTY Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue added to case. [00-2446] (mlyn) [00-2446]

DATE	PROCEEDINGS
1/18/01	ORDER filed granting motion of the Amicus parties to file an appendix. [00-2446] (mlyn) [00-2446]
1/18/01	BRIEF filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue in support of appellants. Pages: 29, Copies: 9, delivered by mail. Certificate of service date 1/16/01. [529342-1] [00-2446] (mlyn) [00-2446]
1/18/01	APPENDIX filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue. Copies: 5. Volumes: 1. Delivered by mail, filed. Certificate of service date 1/16/01. [529343-1] [00-2446] (mlyn) [00-2446]
1/22/01	ELECTRONIC DOCUMENT filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue. To replace original disk sent with Amicus brief. Original was in MS Word. [00-2446] (cmpa) [00-2446]
1/24/01	Assigned for the month of March, (3/5/01). [00-2446] (ceca) [00-2446]
2/1/01	ATTORNEY Marinn F. Carlson for Appellee Pharmaceutical Research added to case. [00-2446] (cmpa) [00-2446]
2/1/01	APPEARANCE filed by Marinn F. Carlson for Appellee Pharmaceutical Resea. [534128-1] [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
2/8/01	BRIEF filed by Appellee Pharmaceutical Research. Pages: 40, Copies: 10, delivered by mail. Certificate of service date 2/7/01. [534738-1] Reply brief due 2/22/01. [00-2446] (cmpa) [00-2446]
2/9/01	PARTY Abbott Laboratories, AMGEN, Inc., Bristol-Myers, Glaxo Wellcome PLC, Smithkline Beecham, Johnson & Johnson, Merck Company, Pfizer, Inc., Procter & Gamble Co., Schering Corp added to case. These companies are part of Pharmaceutical Research and Manufacturers of America. [00-2446] (tim) [00-2446]
2/12/01	MOTION filed Edwin D. Schindler. "Motion for Leave to File Amicus Curiae Brief in Support of Plaintiff-Appellee Seeking Affirmance, and for Participation in Oral Argument, Pursuant to Fed.R.App.P. 29(b) and (g)" Certificate of service dated 2/10/01. [00-2446] (cmpa) [00-2446]
2/14/01	RESPONSE faxed and filed by Appellee Pharmaceutical Research. "Response to Amicus Curiae Schindler's Motion for Leave to Participate in Oral Argument" [535686-1]. Certificate of service dated 2/14/01 [536689-1] [00-2446] (cmpa) [00-2446]
2/15/01	BRIEF filed by Amicus Curiae Chamber of Commerce of the United States in support of Appellee Pharmaceutical Research and Manufacturer of America. Pages: 19, Copies: 9, delivered by mail. Certificate of service date 2/14/01. [536917-1] [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
2/15/01	PARTY Added. Amicus Curiae Chamber of Commerce added to case. [00-2446] (cmpa) [00-2446]
2/15/01	DISCLOSURE STATEMENT on behalf of Amicus Curiae Chamber of Commerce of the United States filed. [00-2446] (cmpa) [00-2446]
2/16/01	ELECTRONIC DOCUMENT filed by Amicus Curiae Chamber of Commerce. Disk of Amicus brief. [00-2446] (cmpa) [00-2446]
2/16/01	RESPONSE filed by Appellant Commissioner, Maine Department of Human Services and Attorney General, ME. "Memorandum in Opposition to Motion of Edwin D. Schindler for Leave to File an Amicus Curiae Brief" Certificate of service dated 2/15/01 [537228-1] [00-2446] (cmpa) [00-2446]
2/16/01	PARTY ADDED. Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae 60 Plus Assoc. added to case. [00-2446] (cmpa) [00-2446]
2/16/01	DISCLOSURE STATEMENT on behalf of Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, and Amicus Curiae 60 Plus Assoc. filed. [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
2/16/01	ELECTRONIC DOCUMENT filed by Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae 60 Plus Assoc. Disk to Amicus Curiae Brief. [00-2446] (cmpa) [00-2446]
2/16/01	BRIEF filed by Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae 60 Plus Assoc. in support of Appellee Pharaceutical Research. Copies: 10, delivered by mail. Certificate of service date 2/14/01. [538082-1] [00-2446] (cmpa) [00-2446]
2/20/01	RESPONSE filed by Edwin D. Schindler. "Reply Memorandum of Amicus Curiae Edwin Schindler on Motion for Leave to File Amicus Brief" Certificate of service dated 2/19/01 [537538-1] [00-2446] (cmpa) [00-2446]
2/21/01	APPEARANCE filed by Richard A. Samp and Daniel J. Popeo for Amicus Curiae 60 Plus Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae Kidney Assoc., Amicus Curiae International Patien, Amicus Curiae Allied Educational, Amicus Curiae Washington Legal. [538154-1] [00-2446] (cmpa) [00-2446]
2/22/01	APPEARANCE filed by Steven J. Rosenbaum for Amicus Curiae Chamber of Commerce. [538348-1] [00-2446] (karn) [00-2446]

DATE	PROCEEDINGS
2/22/01	ELECTRONIC DOCUMENT (brief on disk) filed by Appellants Commissioner and Attorney General, ME. [00-2446] (frnk) [00-2446]
2/23/01	ORDER filed. Upon consideration of "Motion For Leave To File Amicus Curiae Brief In Support Of Plaintiff-Appellee Seeking Affirmance, And For Participation In Oral Argument, Pursuant To Fed. R. App. P. 29(b) and (g)," It is ordered that the motion to file an Amicus Brief is hereby granted. The request to participate in oral argument is denied. [00-2446] (bety) [00-2446]
2/23/01	PARTY Amicus Curiae Edwin D. Schindler added to case. [00-2446] (bety) [00-2446]
2/23/01	Brief of Amicus Curiae Edwin D. Schindler in support of plaintiff-appellee seeking affirmance. Pages: 36, (5,969 words) Copies: 10, delivered by mail. Certificate of service date 2/12/01. [538836-1] [00-2446] (bety) [00-2446]
2/23/01	REPLY BRIEF filed by Appellant's Commissioner and Attorney General, ME. Pages: 29, Copies: 10, delivered mail. Certificate of service date 2/22/01. [538878-1] [00-2446] (frnk) [00-2446]
2/27/01	APPEARANCE filed by Steven J. Rosenbaum for Amicus Curiae Chamber of Commerce of the United States. [539456-1] [00-2446] (cmpa) [00-2446]
2/27/01	APPEARANCE filed for Amicus Curiae Edwin D. Schindler, pro se. [541125-1] [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
3/5/01	CASE ARGUED 03/05/01. Bownes, Keeton, Saris, JJ. (ceca) [00-2446]
5/16/01	OPINION filed. Senior Circuit Judge Bownes, District Court Judge Keeton, and District Court Judge Saris. Signed Judge Hugh H. Bownes, aut PUBLISHED. [563283-1] [00-2446] (cmpa) [00-2446]
5/16/01	JUDGMENT entered by Senior Circuit Judge Bownes, District Court Judge Keeton, and District Court Judge Saris closing case. The Judgment of the district court is reversed and the temporary injunction is vacated. [563284-1] [00-2446] (cmpa) [00-2446]
5/30/01	PETITION filed by Appellee Pharmaceutical Reseach and Manufacturers of America's for rehearing en banc. [567137-1] [00-2446] Certificate of Service dated 5/29/01. [00-2446] (mlyn) [00-2446]
6/7/01	LETTER filed by Computer Research Services. Research firm writes, "Please forward copies of the following documents..." [00-2446] (cmpa) [00-2446]
6/12/01	SUPPLEMENTAL AUTHORITY pursuant to FRAP 28j filed by Appellee Pharmaceutical Research. Certificate of Service 6/11/01 [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
6/13/01	ORDER. Senior Circuit Judge Hugh H. Bownes, District Court Judge Robert E. Keeton, District Court Judge Patti B. Saris. The panel that heard this case has voted to deny the petition for panel rehearing. For the following reasons, there can be no action taken on the petition for rehearing en banc. None of the members of the panel are eligible to vote on the petition for rehearing en banc. Federal Rule of Appellate Procedure 35(a) provides in pertinent part: When Hearing or Rehearing En Banc May Be Ordered. A majority of the circuit judges who are in regular active service may order that an appeal or other proceeding be heard or reheard by the court of appeals en banc. See United States v. Leichter, 167 F.3d 667 (1st Cir. 1999) (absolute majority of active judges is needed to grant rehearing en banc). -2- Judges Keeton and Saris are United States District Court Judges and Judge Bownes is a Senior Circuit Court Judge. All of the active Circuit Court Judges with the exception of Chief Judge Torruella have recused themselves from this case. The petition for rehearing en banc must, therefore, be denied. Chief Judge Torruella wants to be recorded as voting "in favor of rehearing en banc, based on the opinion of the District Court." Judgment shall issue in accord with the Rules. [00-2446] (cmpa) [00-2446]
6/19/01	MOTION filed by Appellee Pharmaceutical Research. "Plaintiff-Appelee's Motion to Stay the Mandate Pending Filing of a Petition for Writ of Certiorari." [572393-1] Certificate of service dated 6/19/01. [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
6/29/01	Defendants-appellants' opposition to plaintiff-appellee's motion to stay the mandate [572393-1]. Certificate of service dated 6/28/01 [574576-1] [00-2446] (bety) [00-2446]
7/3/01	ORDER filed by Senior Circuit Judge Hugh H. Bownes, District Court Judge, and District Court Judge Robert E. Keeton. Mandate is stayed for 28 days to July 31, 2001. (cmpa) [00-2446]
7/13/01	RECORD filed: 2 vol(s). Documents 33-59. Filed in lead case 00-2446. [577814-1] [01-2006, 00-2446] (cmpa) [00-2446 01-2006]
7/17/01	MOTION filed by Appellant Edwin D. Schindler. "Motion to Dismiss for Lack of Appellate Jurisdiction or, in the Alternative, for Transfer to the United States Court of Appeals for the Federal Circuit" Certificate of Service dated 07/16/01. (cmpa) [00-2446]
7/25/01	MOTION filed by Amicus Curiae Edwin D. Schindler. "Motion to Stay Mandate Pending Determination on Pending Motion to Dismiss for Lack of Appellate Jurisdiction..." to further stay mandate until 7/24/01 Certificate of service dated 7/24/01 . [00-2446] (cmpa) [00-2446]
7/30/01	RESPONSE filed by Attorney General, ME. LETTER filed by State of Maine. The Attorney General's Office responds to the motions Edwin Schindler has filed in 00-2446 and 01-2006. Certificate of service dated 7/27/01 [581972-1] [00-2446, 01-2006] (cmpa) [00-2446 01-2006]

DATE	PROCEEDINGS
7/30/01	REPLY filed by Amicus Curiae Edwin D. Schindler. "Reply to Maine's Letter of July 27, 2001 on the Pending Motion to Dismiss for Lack of Appellate Jurisdiction or, in the Alternative, for Transfer to the United States Court of Appeals for the Federal Circuit" Certificate of service dated 7/28/01 [581982-1] [00-2446] (cmpa) [00-2446]
7/31/01	LETTER filed by Daniel M. Price. Appellee PhRMA has filed a Petition for a Writ of Certiorari at the United States Supreme Court. Counsel writes that "PhRMA's filing today in Washington D.C. automatically extends that stay until the Supreme Court disposes of the petition." [00-2446] (cmpa) [00-2446]
8/3/01	U.S. SUPREME COURT NOTICE filed regarding petition for writ of certiorari. Filed in the Supreme Court on [583793-1] 08/01/01. Supreme Court case number: 01-188. [00-2446] (cmpa) [00-2446]
8/13/01	ORDER filed by Chief Judge Hugh H. Bownes. Upon consideration of "Motion to Dismiss for Lack of Appellate Jurisdiction or, in the Alternative, for Transfer to the United States Court of Appeals the Federal Circuit" and response, It is hereby ordered that said motion is denied. (cmpa) [00-2446]
8/13/01	ORDER filed by Chief Judge Hugh H. Bownes. Upon consideration of the motion to further stay mandate and response, it is ordered that said motion be denied. (cmpa) [00-2446]

DATE	PROCEEDINGS
8/13/01	MANDATE ISSUED. [00-2446] (cmpa) [00-2446]
8/13/01	RECORD retained for companion case number(s): 01-2006. Record remains filed under 00-2446. [00-2446] (cmpa) [00-2446]
8/21/01	MOTION filed by Appellee Pharmaceutical Resea in 00-2446 to recall mandate. Certificate of service dated 8/20/01. [00-2446] (cmpa) [00-2446]
8/27/01	ORDER filed by Senior Circuit Judge Hugh H. Bownes. The Order of August 13, 2001 issuing the mandate is hereby rescinded. (cmpa) [00-2446]
8/27/01	ORDER filed by Senior Circuit Judge Hugh H. Bownes. The Motion to Stay Mandate filed by Amicus Curiae Edwin R. [sic] Schindler is hereby denied. (cmpa) [00-2446]
5/13/02	PUBLIC NOTE: "Notice of Change of Address" Daniel M. Price and Marinn F. Carlson have moved their practices to the law firm of Sidley Austin Brown & Wood LLP in Washington, D.C. their new address is: Sidley Austin Brown & Wood LLP, 1501 K Street NW, Washington, D.C. 20005. Tel: 202-736-8000 Fax: 202-736-8711. [00-2446] (cmpa) [00-2446]
5/20/02	ATTORNEY MOTION filed by Allen S. Rugg for Appellee Pharmaceutical Research. "Motion for Leave to Withdraw" Certificate of service dated 5/17/02. [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
5/22/02	ORDER. Leave is hereby granted Attorney Allen S. Rugg to withdraw as counsel for the appeilee, Pharmaceutical Research & Manufacturers of America. (cmpa) [00-2446]
7/5/02	U.S. SUPREME COURT ORDER granting petition for writ of certiorari filed in the Supreme Court on 06/28/02. (cmpa) [00-2446]
7/15/02	RECORD returned to originating court. Debbie Whitney at the district court has requested that this record be sent back. The mandate has not issued. ** Documents 1-60; Hearing on Preliminary Injunction held on 10/19/00 ** (cmpa) [00-2446]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
1100 Fifteenth Street, N.W.
Washington, DC 20005

Plaintiff,

v.

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine
221 State Street
Augusta, Maine 04333

ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine
6 State House Station
Augusta, Maine 04333

Defendants.

Civil Action No. _____

COMPLAINT FOR DECLARATORY, INJUNCTIVE AND OTHER RELIEF

Plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), by its undersigned attorneys, states in support of this Complaint as follows:

INTRODUCTION

1. This is an action for declaratory, injunctive and other relief brought by PhRMA against Defendant Kevin Concannon, the Commissioner of the Department of Health and Human Services of the State of Maine, in his official capacity, and against Defendant Andrew Ketterer, Attorney General of the State of Maine, in his official capacity. Plaintiff seeks injunctive and declaratory relief barring the implementation and enforcement of specified provisions of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter the "Act," provisions hereinafter cited to Section ____ of 22 M.R.S.A., copy attached as Exhibit A hereto), and declaring them unlawful.

2. The challenged provisions of the Act (1) require drug manufacturers to finance drug discounts to Maine residents, and threaten to restrict Maine Medicaid beneficiaries' access to the manufacturers' drugs; (2) punish drug manufacturers for charging prices and realizing profits that the State deems to be excessive, even in out-of-state transactions; and (3) punish drug manufacturers for rearranging their affairs so as to minimize their exposure to these provisions of the Act while continuing to ensure that their drugs will be available to Maine residents.

3. The challenged provisions of the Act violate the Commerce Clause of the United States Constitution by regulating transactions that occur outside Maine, by tying the discounts that drug manufacturers must provide for drugs dispensed in Maine to price discounts provided in other jurisdictions, and by preventing drug manufacturers from modifying their channels of distribution in response to the Act.

4. The challenged provisions of the Act also violate the Supremacy Clause of the United States Constitution by imposing restrictions on patients' access to manufacturers'

drugs in the federal Medicaid program to punish manufacturers who do not participate in the new Maine drug program.

PARTIES

5. Plaintiff, PhRMA, is a non-profit corporation, organized and existing under the laws of the State of Delaware.

6. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA's member companies account for more than 75 percent of brand name drug sales in the United States.

7. PhRMA serves as the pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA is committed to, *inter alia*, advancing public policies that foster continued innovation, educating the public about the drug development and discovery process, and promoting a fair and competitive marketplace. PhRMA has represented its members in connection with the Maine Legislature's consideration of legislation regulating prescription drugs, including the legislation ultimately enacted as the Act challenged here.

8. All of PhRMA's members have their principal places of business outside Maine. By far the greatest part of PhRMA's members' prescription drug sales are to wholesalers and other entities located outside Maine. With limited exceptions, PhRMA's members are not parties to sales transactions occurring in, or with purchasers in or from, the state of Maine.

9. PhRMA brings this suit on behalf of its members. At least one of PhRMA's members possesses standing to sue in

its own right; the regulation of prescription drug pricing is of vital concern to PhRMA's members; and neither the claim asserted nor the relief demanded necessitates the participation of individual PhRMA members.

10. Defendant Kevin Concannon is the Commissioner of the Department of Human Services (hereinafter the "Department") for the State of Maine. Defendant Concannon is sued in his official capacity only.

11. Pursuant to the Act, Defendant Concannon (hereinafter, the "Commissioner") is responsible, directly and through his Department, for the implementation and, in substantial part, enforcement of the Act.

12. Defendant Andrew Ketterer is the Attorney General of the State of Maine. Defendant Ketterer is sued in his official capacity only.

13. Pursuant to the Act, Defendant Ketterer (hereinafter, the "Attorney General") is responsible for the enforcement of the profiteering provisions of the Act.

JURISDICTION

14. Subject matter jurisdiction is founded on 28 U.S.C. §§ 1331 and 1343 because this case arises under the Constitution and laws of the United States.

15. This Court has authority to grant declaratory relief pursuant to 28 U.S.C. §§ 2201 and 2202.

VENUE

16. Venue is proper in this Court under 28 U.S.C. § 1391(b) because the Defendants maintain their offices within this judicial district and because the events giving rise to the claims herein occurred within this judicial district.

THE MAINE Rx LAW

17. The Act, which was not accorded the regular public hearing and public work session processes of the Maine Legislature, enacts a new Chapter 603, entitled "Prescription Drug Access," in Maine Rev. Stat. Ann. Title 22.

18. Chapter 603 includes among its principal components (1) a mandatory prescription drug "rebate" program, and (2) penalties for "profiteering" in prescription drugs (including penalties for taking actions to minimize exposure to the Act).

The Maine Rx Program

19. Subchapter I (§ 2681) of the new Chapter 603 establishes the "Maine Rx Program," a prescription drug rebate program administered by the State (specifically, by the Department) for "qualified" Maine residents.

20. As administered by the Department, the class of "qualified" Maine residents will include the 325,000 Maine residents who do not have prescription drug coverage under other public or private programs.

21. Under the new Maine Rx Program, drug manufacturers are required to remit payments to Maine called "rebates." Maine in turn is required to use these payments to finance discounts provided by retail pharmacies to enrollees in the Maine Rx Program. The Act, through the "rebate" mechanism, thereby effectively transfers to Maine residents a portion of the purchase price received by the manufacturers from their customers (typically wholesalers and distributors). As the Program is being administered by the Department, manufacturers are required to remit these payments regardless of whether their sales occurred outside Maine.

22. In particular, Section 2681(3) requires all prescription drug manufacturers and labelers whose drugs are sold in Maine through publicly supported pharmaceutical assistance programs, such as the federal Medicaid program, to enter into

agreements with the Department to provide such "rebates" for their prescription drugs that are dispensed to Maine residents under the Maine Rx Program.

23. PhRMA members participate in Medicaid.

24. PHRMA members also participate in Maine's Elderly Low-Cost Drug Program (hereinafter the "Elderly LCD Program"), a publicly supported pharmaceutical assistance program.

25. The PhRMA members who participate in these publicly supported pharmaceutical assistance program in Maine are thus required by Section 2681(3) to enter into rebate agreements for the Maine Rx Program.

26. The Act directs the Commissioner to negotiate the amount of the rebate required from each manufacturer under the obligatory rebate agreement.

27. The Act directs the Commissioner to use his "best efforts" to obtain an initial rebate for the Maine Rx Program equal to or greater than the manufacturer's nationwide, statutorily-specified federal Medicaid rebate. Such initial rebates are to take effect beginning January 1, 2001.

28. On August 2, 2000 the Commissioner presented pharmaceutical manufacturers with a "Rebate Agreement," for signature no later than November 1, 2000, that requires payment of "the Medicaid Rebate amount" on drugs dispensed under the Maine Rx program.

29. The Act also directs the Commissioner to negotiate for further rebates, to take effect no later than October 1, 2001, that are equal to or greater than any discount, rebate or price the manufacturer gives in connection with any federal program.

30. If a manufacturer does not enter into a Maine Rx rebate agreement, the Department is directed by Sections 2681(7) and 3174-Y to impose a "prior authorization" requirement on

the manufacturer's drugs that are dispensed—not under the Maine Rx program—but under the entirely distinct federal Medicaid drug program.

31. Prior authorization is intended to limit access to a drug. It does so by requiring a physician who wishes to prescribe the drug to Medicaid patients to justify his or her reasons for doing so to the state Medicaid Administrator on a case-by-case basis in order to obtain specific prior permission from the Administrator. Absent such authorization, the Medicaid patient will not receive coverage for the prescription.

32. The Act's rebate requirement is conjoined with prohibitions on "profiteering" (discussed *infra* at paragraphs 38-46) that, *inter alia*, prevent manufacturers from rearranging their affairs to minimize their exposure to the rebate requirement while continuing to make their drugs available to Maine residents.

33. With the exception of an initial loan from the Trust Fund for a Healthy Maine in fiscal year 2000-01, which must be repaid in fiscal year 2002-03 using rebate revenues collected from manufacturers, the Maine Rx program is to be funded exclusively by the manufacturers' rebate payments through the establishment of the "Maine Dedicated Fund."

34. Maine Rx is thus a pass-through program, under which the State itself does not purchase prescription drugs or contribute state funds to subsidize prescription drug purchases by residents covered by the Maine Rx Program.

35. In addition to establishing the new Maine Rx Program, the Act (Section 254 ss. 8-A) revises the State's existing, voluntary Elderly LCD Program to make participation mandatory for all manufacturers who participate in Medicaid.

36. The Elderly LCD Program receives state funding support.

37. Under the Maine Elderly LCD Program, manufacturers give the State rebates equivalent to those calculated under Medicaid.

Anti-Profiteering

38. Section 2697 declares unlawful the act of "profiteering" in prescription drugs.

39. Manufacturers, labelers, and distributors of prescription drugs are deemed to engage in "illegal profiteering" if they: (1) exact or demand an "unconscionable" price; (2) exact or demand prices or terms that lead to an "unjust or unreasonable" profit; (3) "discriminate[] unreasonably" in selling or distributing drugs dispensed in Maine; or (4) intentionally restrict the sale or distribution of drugs in Maine in retaliation for the Act.

40. The Act's anti-profiteering prohibitions relating to prices, profits, and preferential terms, Sections 2697(A)-(C), are not by their terms confined to transactions occurring in Maine.

41. The Act's fourth anti-profiteering provision, Section 2697(D), precludes manufacturers from rearranging their affairs so as to minimize exposure to the rebate requirement and the anti-profiteering provisions.

42. Violations of the anti-profiteering provisions are punishable by, *inter alia*, injunctive relief, treble damages, punitive damages, and civil penalties of up to $100,000 per violation, plus costs and attorney's fees.

43. Violations of the anti-profiteering provisions of the Maine Rx Law are also deemed to violate the Maine Unfair Trade Practices Act.

44. Violations of the Maine Unfair Trade Practices Act are punishable by, *inter alia*, injunctive relief, damages, restitution, and civil penalties of up to $10,000 per violation.

45. The Attorney General is responsible for investigating suspected violations of the Act's anti-profiteering provisions and the Maine Unfair Trade Practices Act, and for prosecuting civil violations thereof.

46. Violations of the Maine Unfair Trade Practices Act are also subject to private actions for damages, restitution, and equitable relief. Successful plaintiffs may also recover attorney's fees and costs.

THE FEDERAL MEDICAID PROGRAM

47. Medicaid is a federally mandated, state-administered program that operates under federal guidelines to provide medical care to certain low-income populations. The program is jointly funded by the federal and state governments.

48. In 1991 Congress supplemented the federal Medicaid health care program with a rebate program to offset the costs of prescription drug coverage, which states may opt to offer to Medicaid beneficiaries. Omnibus Budget Reconciliation Act ("OBRA") of 1990, enacting § 1927 of the Social Security Act, 42 U.S.C. § 1396r-8.

49. Under the Medicaid drug program, drug manufacturers enter into national rebate agreements with the Secretary of the Department of Health and Human Services. 42 U.S.C. § 1396r-8(a)(1). Pursuant to those agreements, manufacturers pay statutorily-calculated rebates directly to each state for their drugs dispensed to Medicaid beneficiaries in the state. 42 U.S.C. § 1396r-8(b), (c); 56 Fed. Reg. 7049 (1991). The states also receive federal Medicaid reimbursement funds for those drugs, and contribute state funds to make up the balance (such that the Medicaid beneficiary makes no more than a nominal payment).

50. For each drug, a manufacturer pays the same nationwide Medicaid rebate. 42 U.S.C. § 1396r-8(c)(1)(A).

51. The formula for calculation of that rebate is prescribed by statute. 42 U.S.C. § 1396r-8(c)(1).

52. The calculation of the rebate starts with the per-unit Average Manufacturer Price ("AMP") paid by wholesalers, taking into account all discounts and price reductions, for drugs in the "retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1).

53. The manufacturer's Medicaid rebate for brand-name drugs is the greater of: (1) 15.1% of the AMP or (2) the difference between the AMP and the manufacturer's nationwide "best price." 42 U.S.C. § 1396r-8(c)(1). Thus if any U.S. purchaser (with certain statutory exceptions) pays less than 84.9% of the AMP for the brand-name drug, the Medicaid rebate paid by the manufacturer will be based on that best price. The Medicaid rebate for generic and over-the-counter drugs is 11% of AMP. 42 U.S.C. § 1396r-8(c)(3).

COUNT I
VIOLATION OF COMMERCE CLAUSE
Section 2697(2)

54. Paragraphs 1-53 are incorporated by reference.

55. The Commerce Clause of the United States Constitution prohibits a state from regulating transactions occurring outside of the state.

56. The "anti-profiteering" provisions of the Act subject manufacturers to penalties with respect to prices, profits, and terms of sales occurring outside Maine.

57. These provisions (Section 2697(2)) violate the Commerce Clause.

58. PhRMA has no adequate remedy at law.

COUNT II
VIOLATION OF COMMERCE CLAUSE
Sections 2681(3) and 254 ss8-a

59. Paragraphs 1-58 are incorporated by reference.

60. The Commerce Clause of the United States Constitution prohibits a state from regulating transactions occurring outside of the state.

61. The rebate provisions of the Act effectively regulates the prices received by drug manufacturers from their customers in transactions occurring outside of Maine.

62. The rebate provisions (Sections 2681(3) and 254 ss8-A) violates the Commerce Clause.

63. PhRMA has no adequate remedy at law.

COUNT III
VIOLATION OF COMMERCE CLAUSE
Section 2681(4)

64. Paragraphs 1-63 are incorporated by reference.

65. The Commerce Clause prohibits a state from tying in-state prices to prices charged in other jurisdictions.

66. The rebate provision of the Act ties prices in Maine to prices paid in other jurisdictions by using as benchmarks for the Maine Rx program rebates the nationwide, federal Medicaid rebate, and nationwide rebates and discounts under other federal programs.

67. The rebate provision (Section 2681(4)) violates the Commerce Clause.

68. Plaintiff has no adequate remedy at law.

COUNT IV
VIOLATION OF COMMERCE CLAUSE
Section 2697(2)(D)

69. Paragraphs 1-68 are incorporated by reference.

70. The Commerce Clause prohibits a state from interfering with "the mobility of [interstate] commerce."

71. The "anti-retaliation" profiteering provision of the Act prohibits drug manufacturers from arranging their interstate distribution channels in response to the Act.

72. The "anti-retaliation" profiteering provision (Section 2697(2)(D)) violates the Commerce Clause.

73. PhRMA has no adequate remedy at law.

COUNT V
VIOLATION OF THE SUPREMACY CLAUSE
Sections 2681(7) and 3174-Y

74. Paragraphs 1-73 are incorporated by reference.

75. The Supremacy Clause prohibits state laws that conflict with federal laws and programs.

76. The prior authorization provisions of the Act conflicts with federal Medicaid law and the federal Medicaid program by curtailing Maine Medicaid beneficiaries' access to a manufacturer's drugs to punish its failure to finance discounts under the Maine Rx Program.

77. The prior authorization provisions (Sections 2681(7) and 3174-Y) violates the Supremacy Clause.

78. PhRMA has no adequate remedy at law.

COUNT VI
VIOLATION OF 42 U.S.C. § 1983

79. Paragraphs 1-78 are incorporated by reference.

80. The Commissioner and the Attorney General are State officials acting within the scope of their authority in implementing the Act.

81. The Act deprives Plaintiff's members of the rights, privileges, and immunities secured by the Commerce Clause and the Supremacy Clause of the U.S. Constitution.

82. The Commissioner and the Attorney General are liable to Plaintiff for proper redress under 42 U.S.C. § 1983.

RELIEF REQUESTED

WHEREFORE, Plaintiff, Pharmaceutical Research and Manufacturers of America respectfully requests the following relief:

A. A declaratory judgment, pursuant to 28 U.S.C. § 2201, that Sections 254 ss8-A, 2681(3), 2681(4), 2681(7), 2697, and 3174-Y of the Act violate the United States Constitution and are unenforceable;

B. A preliminary and permanent injunction enjoining the Defendants from implementing or enforcing the Act;

C. An order awarding PhRMA's costs and attorneys' fees pursuant to 42 U.S.C. § 1988; and

D. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/

Bruce C. Gerrity, Esq.
Ann R. Robinson, Esq.
Preti, Flaherty, Beliveau,
Pachios & Haley, LLC
45 Memorial Circle
P.O. Box 1058
Augusta, ME 04332-1058
(207) 623-5300

Attorneys for Plaintiff,
Pharmaceutical Research and
Manufacturers of America

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Washington, DC 20004
(202) 347-0066

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA Plaintiff, v.	*	Civil Action No. _____
KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine Defendants.	*	

DECLARATION OF RICHARD A. FELDMAN

1. My name is Richard A. Feldman. From December 1996 to present, I have served as the Executive Director, Trade and Pharmacy Affairs for Roxane Laboratories, Inc. (hereinafter "Roxane"), an affiliated company of Boehringer Ingelheim Pharmaceuticals, Inc. (hereinafter "Boehringer"). I am responsible for the retail distribution of product for both Roxane and Boehringer (collectively referred to as "Companies").

2. Boehringer is a corporation organized and existing under the laws of Delaware that maintains its principal place of business in Ridgefield, Connecticut.

3. Roxane is a corporation organized and existing under the laws of Delaware that maintains its principal place of business in Columbus, Ohio.

4. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").

5. I am knowledgeable about Companies' distribution system, sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Companies' sales of prescription drugs in Maine.

6. With the exception of sales transactions described in paragraphs 7 and 8, sales of Companies' prescription drugs occur outside Maine. Companies' warehouses located in Columbus, Ohio and Reno, Nevada receive and fill orders from wholesalers, distributors and warehousing retail chains. The warehouses then ship the orders via common carrier to the requesting entity located at a location outside the state of Maine. Title to the prescription drugs passes to the wholesaler or distributor upon delivery to the carrier. The wholesalers, distributors and warehousing retail chains then sell the prescription drugs to retail stores located throughout the country, including the state of Maine. The wholesalers and distributors do not act on behalf of Companies in the resale of the prescription drugs.

7. Companies sell prescription drugs to one warehousing retail chain, Hannaford Brothers, in Scarborough, Maine. Companies ship the prescription drugs and send invoices directly to Hannaford Brothers.

8. Bindley Western Drug Company ("Bindley"), a wholesaler based in Indianapolis, Indiana, directs that Companies ship prescription drugs directly to its subsidiary, JE Gould, in Westbrook, Maine. However, Bindley is

invoiced and the title to the drugs shipped to JE Gould passes to Bindley.

9. Other than as described in paragraphs 7 and 8 of this declaration, Companies make no direct sales or shipments of prescription drugs in the State of Maine.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August 8, 2000

/s/
Richard A. Feldman

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
1100 Fifteenth Street, N.W.
Washington, DC 20005

Plaintiff,

v.

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine
221 State Street
Augusta, Maine 04333

ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine
6 State House Station
Augusta, Maine 04333

Defendants.

* * * * * * *

Civil Action No. _____

DECLARATION OF RUSSEL A. BANTHAM

1. My name is Russel A. Bantham. From 1995 to present, I have served as Senior Vice-President and General Counsel of the Pharmaceutical Research and Manufacturers of America ("PhRMA").

2. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the

enforcement of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Act").

3. PhRMA is a non-profit corporation organized and existing under the laws of the State of Delaware. PhRMA's offices are located in Washington, D.C.

4. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, happier, and more productive lives. Together these companies account for over 75% of the sales of brand name drugs in the United States.

5. PhRMA serves as the pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA is committed to, *inter alia*, advancing public policies that foster continued innovation, educating the public about the drug development and discovery process, and promoting a fair and competitive marketplace. PhRMA has represented its members in connection with the Maine Legislature's consideration of legislation regulating prescription drugs, including the legislation ultimately enacted as the Act challenged here.

6. All of PhRMA's members have their principal places of business outside Maine.

7. PhRMA is authorized by its Board of Directors to bring this suit on behalf of its members. The regulation of prescription drug pricing is of vital concern to PhRMA's members.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August __, 2000

/s/
Russel A. Bantham

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA Plaintiff, v.	*	Civil Action No. _____
KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine Defendants.	*	

DECLARATION OF GEORGE BILYK

1. My name is George Bilyk. From August 1996 to present, I have served as the Senior Director, Medicaid and Medicare business of Janssen Pharmaceutica, Inc. ("Janssen"). Prior to my current position, I was Marketing Controller for Janssen from February 1992 until February 1994 and Managed Care finance controller from February 1994 until August 1996.

2. Janssen is a corporation organized and existing under the laws of Pennsylvania that maintains its principal place of business in Titusville, New Jersey. Janssen is a wholly

owned subsidiary of Johnson & Johnson, a New Jersey corporation that maintains its principal office in New Brunswick, New Jersey.

3. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").

4. I am knowledgeable about Janssen's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Janssen's sales of prescription drugs in Maine. All sales of Janssen's prescription drugs occur outside Maine. Janssen's distribution center is located in Franklin, New Jersey from which it fills all orders from wholesalers and distributors. In accordance with Janssen's standard terms and conditions of sale pursuant to which it sells its products to its customers including wholesalers and distributors ("Terms and Conditions"), Janssen delivers the prescription drugs to its wholesalers and distributors at the loading dock of Janssen's distribution center in New Jersey and all sales are FOB, shipping point (i.e. Janssen's distribution center in Franklin, New Jersey). Title and risk of loss passes to the customer at the loading dock in New Jersey. A copy of Janssen's Terms and Conditions is attached to this declaration as Exhibit A. Wholesalers and distributors make payments in New Jersey for the prescription drugs purchased. Wholesalers and distributors re-sell Janssen's prescription drugs to their customers who are located throughout the country, including customers in the state of Maine. The wholesalers and distributors do not act on behalf of Janssen in the resale of the prescription drugs.

5. As far as I am aware only two customers, Bindley Western Drug Company and Progressive Distributors, Inc. operate warehouse and distribution facilities in Maine. However, once again, pursuant to Janssen's Terms and

Conditions its sales to these distributors take place in New Jersey.

6. When a prior authorization (a "PA") is required for a prescription drug under a plan providing prescription drug coverage, a physician must obtain specific permission from the plan each time the physician wishes to prescribe the drug, or the pharmacist must obtain specific permission from the plan each time the pharmacist is asked to fill a prescription for the drug. Imposition of a prior authorization requirement with respect to a particular drug severely curtails access to the drug for covered patients and sharply reduces the drug's market share and sales, as the PA causes a shift of patients to competing drugs of other manufacturers that are not subject to a PA. Because a PA imposes additional procedural burdens on physicians prescribing the manufacturer's drug and retail pharmacies dispensing it, the effect of a PA is to diminish the manufacturer's goodwill that helped foster demand for its drug over competing drugs produced by other manufacturers, and to shift physician and patient loyalty to those competing drugs, perhaps permanently.

7. Based upon Janssen's experience with PA's, if the Maine Department of Human Services imposes PA requirements on Janssen's prescription drugs in the Medicaid program pursuant to § 2681(7) of title 22 of the Maine Revised Statutes, patient access to those drugs will be sharply curtailed and the market share and sales of those drugs will be severely reduced, causing Janssen substantial injury. This injury resulting from a PA authorized by § 2681(7) while the PA is in place is certain to occur and is likely to be substantial.

8. Once market share is lost, it is difficult to recover and may never be recovered, as physicians and patients develop loyalty to competing manufacturers' prescription drugs not subject to the PA while the PA on the manufacturer's drug is in place. The result for the manufacturer whose drug is subject to the PA may be a permanent loss of sales, market

share, and good will. This lingering injury to a drug manufacturer resulting from a PA under § 2681(7) is certain to occur and is likely to be substantial.

9. On August 4, 2000 Janssen's sister company, Johnson & Johnson Health Care Systems, received the letter dated August 2, 2000 from Kevin W. Concannon, Commissioner of the State of Maine Department of Human Services, a true copy of which is attached to this declaration as Exhibit B.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August 9, 2000

/s/
George Bilyk

[Exhibit A]

P.O. Box 401
Raritan, New Jersey
8869-0602

JANSSEN ORTHO-McNEIL Centocor
PHARMACEUTICA

Invoice

Bill To:

Ship To:

Purchase Order #	Invoice	Invoice Date	Terms of Payment	Due Date

NDC/UPC		Product Description	Quantity	Unit	Unit Price	Net Amount	Tax

Controlled Substance Schedule	DEA 222 Form	Customer DEA #	

Payments must be received in our bank by the Due Date In order to earn the discount.
Please mail your payments 3-5 days prior to the Due Date.
No Anticipation.
Post Audit claims will not be honored. A-061

TERMS AND CONDITIONS OF SALE

Any statement contained on any purchases order or similar document, which is not specifically approved or acknowledged in writing by Seller, will not be considered as part of the agreement between the parties.

All orders are subject to acceptance at the home office.

Title, Shipment, Delivery: Title to and Risk of loss of Seller's products passes to Purchaser upon delivery to a common carrier. Seller will pay the cost of freight and insurance to Purchaser's location. Purchaser will pay any costs due to special shipping requests. Seller reserves the right to make shipments in installments as it deems advisable or necessary, and all such installments shipped separately will be separately invoiced and paid.

Warranties

Seller warrants that: 1) No article bearing its name (or that of an affiliate) and covered by this invoice is adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, nor is an article which may not, under the provisions of sections 404 or 505 of such Act, be introduced into interstate commerce; 2) No article covered by this invoice is produced in violation of any provisions of the Fair Labor Standards Act on 1936, as amended; 3) The advertising claims, labels, and circulars employed by it do not violate any provisions of the Federal Trade Commission act, as amended. These warranties are in lieu of all other warranties, expressed or implied, including those of merchant ability and fitness for a particular purpose. At Seller's request, Buyer will return any allegedly defective products to Seller.

Limitation of Liability

In no event will Seller be liable for any direct, indirect, special or consequential damages arising out of or in

connection with the sale or use of products including, without limitation, damages resulting from any breach of any obligation imposed on Seller hereunder or in connection herewith. Consequential damages shall include, without limitation, loss of use, Income or profit, or loss or damage to person or property.

Invoicing and Pricing

An invoice is rendered by the Customer Service Department to cover each shipment. Merchandise is invoiced at prices in effect on the day the order is received. Prices are subject to change without notice. No claim for rebate on price declines is allowed, nor do we make claims on Buyer or our product on price advances.

All stated terms are from date of invoice, and payment must be received by the due date to earn the cash discount. Neither anticipation nor post audit claims are honored. To qualify for adjustments, report all discrepancies on this invoice within 15 days. No statement will be rendered; kindly remit from this invoice.

Taxes

Any tax, duty, custom or other fee of any nature imposed upon this transaction by any federal, state or local government authority shall be paid by Buyer in addition to the price quoted or invoiced. In the event Seller is required to prepay any such tax, Buyer will reimburse Seller.

Prescription Products

Any product named on this invoice and labeled "Caution: Federal law prohibits dispensing without prescription," is sold for such use only.

[Exhibit B]

Angus S. King, Jr.
Governor

Kevin W. Concannon
Commissioner

State Of Maine
DEPARTMENT OF HUMAN SERVICES
Augusta, Maine 04333

August 2, 2000

BARBARA DYMOND
JOHNNSON&JOHNSON HEALTH CARE SYSTEMS INC
1000 RT. 202 SOUTH
P.O. BOX 300
RARITAN, NJ 088690602

Dear BARBARA DYMOND,

I am writing to you on behalf of the State of Maine, Department of Human Services. I want to inform you about the new Maine Rx Program and invite you to participate in the rebate program for this initiative. I am enclosing a copy of the law, Public Law 1999, chapter 786, for your review.

The Governor and the Legislature passed this new law, during the past legislative session, which goes into effect on January 1, 2001. Under the Maine Rx program the State will serve as a pharmaceutical benefit manager (PBM) for the estimated 325,000 Maine residents who have no prescription drug benefit as part of a private or public health insurance program. Those residents would be eligible to receive a Maine Rx card.

The Maine Rx Program would provide your company's products to an ever growing population and a population that would exceed the current Medicaid population, which is currently 170,000 people. This means greater access to and utilization of your pharmaceuticals.

You will also find a rebate agreement enclosed. I am requesting you sign and return this agreement as soon as possible, but not later than November 1, 2000, so your company's products may be included in the Maine Rx Program for the January 1, 2001 start date. This law also addresses profiteering, unfair trade practices, and requires the Department impose prior authorization requirements in the Medicaid Program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers who do not enter into rebate agreements.

Also to be noted, the names of manufacturers and labelers who do not enter into rebate agreements pursuant to this law are public information. Your company has the opportunity to assist those Maine citizens with a real need for affordable prescription drugs. An added benefit to participating is your company gains nationwide recognition as a participant in the Maine Rx Program. This Program has received nationwide press attention and will continue to do so in the foreseeable future.

Thank you for your continued support of Maine Pharmacy Programs and for your concern for the prescription drug needs of all Maine citizens.

We look forward to working with you, and should you have any questions concerning this Program, feel free to call Jude Walsh, Director, Division of Quality Improvement at (207)287-1815 for our direct assistance.

Sincerely,

/s/
Kevin W. Conannon, Commissioner

Enclosures: PL 786
Rebate Agreement

MAINE RX PROGRAM REBATE AGREEMENT

BETWEEN

THE COMMISSIONER OF THE DEPARTMENT OF HUMAN SERVICES OF THE STATE OF MAINE

And -

THE MANUFACTURER IDENTIFIED IN SECTION VIII

OF THIS AGREEMENT

(Hereinafter referred to as the "Manufacturer")

The Commissioner, on behalf of the State of Maine, and the Manufacturer, on its own behalf for the purposes of complying with Public Law 1999, chapter 786, hereby agree to the following:

I. DEFINITIONS

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified herein:

(a) "*AVERAGE WHOLESALE PRICE*" means the Wholesale Price charged on a specific commodity that is assigned by the drug Manufacturer and is listed in a nationally recognized drug-pricing file.

(b) "*CALENDAR QUARTER*" means four times a year. Specifically the first Calendar Quarter will be from January 1, 2001 — March 31, 2001. Each successive three-month period shall be a Calendar Quarter.

(c) "*COMMISSIONER*" means the Commissioner of the Department of Human Services.

(d) "*DEPARTMENT*" means the Department of Human Services.

(e) "*MANUFACTURER*" means the entity holding legal title or possession of the National Drug Code (NDC) for the Prescription Drug.

(f) "*NATIONAL DRUG CODE* (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this Agreement, the complete 11-digit NDC will be used including the labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or -formulation), and package size code to identify a prescription drug.

(g) "*NET SALES*" means Calendar Quarter gross sales revenue less cash discounts allowed and all other price reductions which reduce the actual price paid; and as discussed under the definition of WP.

(h) "*PRESCRIPTION DRUG*" means (1) legend drugs, defined as drugs carrying the statement "Caution: Federal Law Prohibits Dispensing Without A Prescription" and (2) any other drugs which by State law or regulation require the prescription of a licensed practitioner for dispensing. For purposes of this Agreement, all Prescription Drugs must be identified by the Manufacturer's labeler code segment of the National Drug Code (NDC).

(i) "*QUALIFIED RESIDENT*" means a resident of the State who has obtained from the Department a Maine Rx enrollment card.

(j) "*REBATE AMOUNT*" means the Medicaid Rebate amount.

(k) "*REBATE PAYMENT*" means, with respect to the Manufacturer's Prescription Drugs, the Calendar Quarter payment by the Manufacturer to the State of Maine

which shall be the sum of the Rebates of each prescription drug (computed for each dosage form and strength of each Prescription Drug) calculated as follows:

(1) The total number of Units paid under the Maine Rx Program for qualified residents during the Calendar Quarter multiplied by the Rebate amount per Unit.

(2) Effective January 1, 2001, a percentage equal to the Medicaid Rebate percentage to the State of Maine in effect for the corresponding time period.

(l) "*UNIT*" means drug Unit in the lowest identifiable amount (i.e. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the Unit for each dosage form and strength of each Prescription Drug in accordance with instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate program under Section 1927 of the Social Security Act.

(m) "*UTILIZATION DATA*" means the information regarding the total number of Units of each dosage form and strength of the Manufacturer's Prescription Drugs paid during the Calendar Quarter under the Program. Drugs dispensed prior to January 1, 2001 are excluded. The Utilization Data includes: (1) 11-digit NDC, including package size code; (2) product name; (3) quantity of Units paid during the Calendar Quarter by 11-digit NDC; (4) total number of prescriptions paid during the Calendar Quarter by 11-digit NDC; and (5) total dollar amount paid during the Calendar Quarter by 11-digit NDC.

(n) "*WHOLESALE PRICE* (WP)" means, with respect to a Prescription Drug of the Manufacturer for a Calendar Quarter the average price paid by Wholesalers in the United States to the Manufacturer, for ultimate

distribution to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to Wholesalers where the drug is relabeled under that distributor's national drug code). WP includes cash discounts allowed and all other price reductions, which reduce the actual price paid. It is calculated as a weighted average of prices for a Manufacturer's package sizes for each Prescription Drug by the Manufacturer during that Calendar Quarter. Specifically it is calculated as Net Sales divided by number of Units sold, excluding drugs or any other items given away but not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the Units of each drug sold under the bundled arrangement. The V/P for a Calendar Quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjusted the prices actually realized.

(o) "*WHOLESALER*" means any entity (including a pharmacy or chain of pharmacies) to which the Manufacturer sells the Prescription Drug, but that does not re-label or repackage the Prescription Drug.

II. MANUFACTURER'S RESPONSIBILITIES

The Manufacturer agrees to the following:

(a) To calculate and to make a Rebate Payment each Calendar Quarter to the State of Maine for the Manufacturer's Prescription Drugs paid for by the Department pursuant to the Maine Rx Program during a Calendar Quarter under the Maine Rx Program as follows:

Manufacturer's first rebate payment for the Calendar Quarter January 1, 2001 through March 31, 2001 shall be due September 30, 2001, or 30 days after receipt of

utilization data pursuant to Section III (a) of this Agreement, whichever is later.

All subsequent Rebate payments will be made by the Manufacturer to the State of Maine within 30 days of the close of each Calendar Quarter, or within 30 days upon receipt of the Utilization. Data pursuant to Section III (a) of this Agreement, whichever is later. Simultaneously, with each Rebate Payment, the Manufacturer will provide the Department with the Manufacturer's most recent price catalog, unless no price changes were made from the previous Calendar Quarter.

(b) To continue to make a Rebate Payment to the State of Maine on all of its Prescription Drugs as defined in this Agreement so long as this Agreement, or a successor Agreement, is in force and as long as such Prescription Drugs are dispensed under the Manufacturer's NDC. If there are no sales by the Manufacturer during a Calendar Quarter the WP used for the most recent Calendar Quarter in which sales occurred will continue to be used in calculating Rebates.

(c) The Manufacturer will be responsible for Rebates on claims for prescription drugs that were dispensed within one year of the date that the claim was paid by the Department.

(d) The Manufacturer agrees to maintain all books, documents, papers, accounting records, and any other evidence pertaining to this Agreement and make such material available at its offices during normal business hours and shall send copies of such material to the Department upon the request of the Department during the period of this Agreement and for a period of two years after the termination of this Agreement. The Manufacturer shall allow inspection of pertinent documents by the Department or any authorized

representative of the State of Maine, and shall furnish copies thereof, if requested.

III. COMMISSIONER'S RIGHTS AND RESPONSIBILITIES

(a) The Department, on behalf of the Commissioner, shall send the Utilization Data as defined in this Agreement, to the Manufacturer, by certified mail, return receipt requested, within 60 days following the last day of each Calendar Quarter for qualified residents. The Commissioner, through the Department, shall maintain electronic claims records for the most recent four Calendar Quarters that will permit the Manufacturer to verify through an audit process The Utilization Data provided by the Department.

(b) The Department shall conduct audits, as it deems necessary to verify rebate calculation and payment.

IV. DISPUTE RESOLUTION FOR DISCREPANCIES IN REBATE AMOUNTS

Discrepancies in Rebate amounts must be resolved using the following process:

(a) If there is a discrepancy in the Manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the Manufacturer or labeler, the Department, at the Department's expense, may hire a mutually agreed-upon auditor. If a discrepancy still exists following the audit, the Manufacturer or labeler shall justify the reason for the discrepancy or make payment to the Department for any additional amount due.

(b) If there is a discrepancy against the interest of the Manufacturer or labeler in the information provided by the Department to the Manufacturer or labeler regarding the Manufacturer's or labeler's Rebate, the Manufacturer or labeler, at the Manufacturer's or labeler's expense,

may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the Department. If a discrepancy still exists following the audit, the Department shall justify the reason for the discrepancy or refund to the Manufacturer any excess payment made by the Manufacturer or labeler.

(c) Following the procedures established in paragraph a or b, either the Department or the Manufacturer or labeler may request a hearing before the Department of Human Services Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

(d) The Manufacturer further agrees that the sole and exclusive means for the presentation of any legal claim against the State arising out of this Agreement shall be in accordance with 5 MRSA section 11001. The Manufacturer further covenants not to initiate legal proceedings in any State or Federal court in addition to, or in lieu of, proceedings under section 11001. This Agreement shall be governed in all respects by the laws, statutes, and regulations of the United States of America and of the State of Maine. The Manufacturer consents to personal jurisdiction in the State of Maine.

(e) Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

V. CONFIDENTIALITY PROVISIONS

(a) Commercial or financial information disclosed by the Manufacturer in connection with this Agreement is confidential information, and will not be disclosed by the Commissioner or the Department (including any auditors or agents thereof) in a form which discloses the identity of a specific Manufacturer or Wholesaler, prices

charged for drugs by such Manufacturer or Wholesaler, in accordance with 42 U.S.C. § 1396r-8(b)(3)(D), 22 M.R.S.A. § 402(3) and Maine Rules of Evidence, Rule 507.

(b) The Manufacturer will guarantee the protection and confidentiality of the Utilization Date, including the proper care, custody, use and preservation of records, papers, files, communications of the Department and any other information that may reveal information related to the Utilization Data. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.

(c) Notwithstanding the non-renewal or termination of the Agreement for any reason, the confidentiality provisions will remain in full force and effect.

VI. TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an indefinite period beginning on January 1, 2001.

(b) The Manufacturer may terminate the Agreement for any reason, and such termination shall become effective the first day of the first Calendar Quarter period beginning sixty (60) days after the Manufacturer gives written notice requesting termination.

(c) The Commissioner may terminate the Agreement for any reason, upon sixty- (60) days prior written notice to the Manufacturer.

(d) The termination of this Agreement by either party will not affect any Rebate payments due to the State of Maine.

(e) In the event that any element of this Agreement is affected by a legislative amendment, including, but not limited to the percentage amount of Rebate required, such amended or revised provisions shall be incorporated by reference within this Agreement and shall supersede any of the conflicting provisions of this Agreement. If either party is unwilling to accept such a change in terms, this Agreement may be terminated pursuant to the terms set out in subsections (a) through (d) above.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Commissioner will be sent to:

Maine Rx Program
Director of Pharmacy Programs
Bureau of Medical Services, 3rd Floor
11 State House Station
Augusta, ME 04333-0011

Notice to the Manufacturer will be sent to the address provided to the Department by the Manufacturer.

(b) In the event of a transfer of ownership of the Manufacturer, this Agreement is automatically assigned to the new owner subject to the conditions specified in this Agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Commissioner under the Constitution, the Social Security Act, other Federal laws or State laws.

(e) The terms "Department" and "Manufacturer" incorporate any contractors or agents thereof, which fulfill responsibilities pursuant to this Agreement unless specifically provided for in the Rebate Agreement.

(f) This Agreement will not be altered except by an amendment in writing signed by both parties and except as indicated in subsection VI (e). No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by a duly appointed representative of the Manufacturer, and the Commissioner, and approved by the Office of the Attorney General.

(g) In the event that a due date falls on a weekend, or a Federal or State holiday, the report or other item will be due on the first business day following that weekend or holiday.

VIII. MANUFACTURER'S ACCEPTANCE

I, _____ hereby agree to the terms
(Name of Authorized Representative)
of this Agreement for the following Manufacturer(s) and labeler(s):

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Signature) (Title)

Date: _____

IX. COMMISSIONER'S CERTIFICATION

This is to certify that _____ is a participant in the Maine Rx Program Rebate Program effective _____.

_____ _____

Christine Zukas-Lessard DATE: _____

Acting Director, Bureau of Medical Services
For the Commissioner

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff,

v.

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine

ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine

Defendants.

Civil Action No. _____

DECLARATION OF THOMAS M MCPHILLIPS

1. My name is Thomas M. McPhillips. I serve as the Senior Director of the U.S. Trade Group of Pfizer Inc. ("Pfizer").

2. Pfizer is a corporation organized and existing under the laws of Delaware that maintains its principal place of business in New York, New York.

3. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for

Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").

4. I am knowledgeable about Pfizer's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Pfizer's sales of prescription drugs in Maine.

5. With the exception of sales transactions described in paragraph 7, sales of Pfizer's prescription drugs occur outside Maine. The Pfizer warehouses located in New Jersey, Tennessee and California fill orders from wholesalers and direct customers. In accordance with its standard published terms of sales to wholesalers and direct customers a copy of which is attached as Exhibit A to this declaration, Pfizer receives orders from wholesalers and other customers by electronic medium, facsimile, mail or telephone at Pfizer's logistics center in Memphis, Tennessee and then routes the orders to appropriate warehouses for processing. The warehouses then ship the orders via common carrier to the customers. The terms of sale state that title to the prescription drugs passes to the wholesaler or direct customer upon delivery to the carrier which is when a sale is recognized. The wholesalers then sell the prescription drugs to their customers who are located throughout the country, including customers in the state of Maine. The wholesaler and distributors do not act on behalf of Pfizer in the resale of the prescription drugs. Direct customers include retail pharmacies, hospitals, public health clinics and other dispensing pharmacies. These customers dispense product based on physician's orders and prescriptions to patients located throughout the United States.

6. Warner Lambert Company is a wholly owned subsidiary of Pfizer. Warner Lambert's operating division, Parke-Davis sells prescription drugs outside of Maine. The Parke-Davis warehouses located in Illinois and Pennsylvania fill orders from wholesalers and direct customers. In accordance with Parke- Davis' standard terms of sales to wholesalers and

direct customers, Parke-Davis ships orders via common carriers to customers. Parke-Davis' terms of sale provide that the prescription drugs are shipped "FOB point of origin." Therefore, title to the products passes to the customers at Parke Davis' warehouses.

7. Pfizer's sales of prescription drugs pursuant to the Federal Supply Schedule are not conducted pursuant to the standard published terms of sale described in Exhibit A. Rather, the title to products sold pursuant to the Federal Supply Schedule passes to Pfizer's customer upon delivery to the customer.

8. On August 4, 2000, Pfizer received the letter dated August 2, 2000 from Kevin W. Concannon, Commissioner of the State of Maine Department of Human Services, a true copy of which is attached to this declaration as Exhibit B.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August 9, 2000

/s/
Thomas M. McPhillips

[Exhibit A]

Pfizer U.S. Pharmaceuticals

Wholesaler Price List

Effective
January 11, 2000

A-078

General Offices:

PFIZER U.S. PHARMACEUTICALS
235 East 42nd Street, New York, New York 10017
(212) 573-2323

DISTRIBUTION CENTERS:

1999 N. Shelby Oaks Drive, Memphis, Tennessee 38134
100 Jefferson Road, Parsippany, New Jersey 07054
16700 Red Hill Avenue, Irvine, California 92714
Toll-Free Order Number (800) 533-4535

BEST AVAILABLE COPY

U.S. Pharmaceuticals

GENERAL INFORMATION: ORDERS AND CORRESPONDENCE

All orders, and any correspondence pertaining thereto, are to be sent to:

Pfizer Inc
Memphis Logistics Center
1855 E. Shelby Oaks Drive
Memphis, TN 38134
Attn: Pharmaceuticals Customer Service
(1-800-533-6535)

All orders, whether issued upon solicitation or not, are subject to acceptance and credit approval by the company. We reserve the right to restrict order quantities.

PRICES
All prices are submitted without offer.

TERMS OF SALE
2% 30 days N.O.I. (date of invoice) net 45 days.
Electronically — 2% 30 days N.O.I. (date of invoice) net 30 days.

MINIMUM ORDER/ORDER FREQUENCY
All orders totaling less than $100.00 net will be subject to a $5.00 service charge. Under both terms, payment must be in the bank on the discount date. Accounts are limited to two orders per week. Orders in excess of the maximum will be subject to a $5.00 service charge.

SHIPPING AND ROUTING
On orders where we pay transportation charges, we reserve the privilege of shipping the number of case sizes shown. Where special handling or routing is requested, the difference in transportation charges will be charged to the customer.

DELIVERY
All deliveries shall be made F.O.B. point of shipment. Title to the goods sold shall pass upon delivery of the goods to the carrier.

DAMAGE OR DELAY IN TRANSIT
If merchandise arrives in broken or damaged condition, insist upon the carrier's agent noting the damage or breakage on the delivery receipt. The transportation company acts as the agent of the purchaser, and we are not responsible for loss of, damage to, or delay regarding the goods after delivery to the carrier. We shall be pleased to make, when requested, in forwarding claims against the carrier, but we cannot assume the responsibility of collecting them.

RETURN GOODS POLICY
Products may be returned on the following basis:

I. Returnable Items: The following products are returnable by customers without prior approval:

A. Outdated and discontinued merchandise, in the original container and bearing the original label.
B. Product damaged in transit, subject to the above paragraph.
C. Material shipped in error by Pfizer.

Note: no refunds will be issued for merchandise returned more than 12 months beyond expiration.

II. Non-Returnable Items: Product other than that listed above is deleted as non returnable. This includes, but is not limited to:

A. In-store product.
B. Packages with label removed.
C. Repackaged product.
D. Products that have been in a fire, storeroom, basement, or similar site.
E. Products sold as a "non-returnable" basis.
F. Products received more than twelve months beyond the expiration date noted on the package. (Products may be returned for shortdate, but no credit will be issued.)
G. Merchandise purchased or otherwise obtained in violation of any Federal, State, or local law or regulation.
H. Merchandise destroyed or damaged from honorable causes such as fire, water, tornado, etc., and merchandise that has otherwise deteriorated due to conditions occurring after shipment and beyond the control of the manufacturer, such as improper storage, heat, cold, smoke, etc.

Note: The Company's determination as to the salvage, credit or exchange value of non-shootlist returned shall be final. The Company reserves the right to destroy returned merchandise without payment or liability.

III. Procedure for Returning Pfizer U.S. Pharmaceutical Group Products:

A. For all customers, returnable items may be returned without prior authorization by Company representatives. Whenever you wish to return these items, pack the material in a container suitable for shipment, and include a packing list that identifies each item being returned, the name and address of your company, and your Pfizer account number. All returns shall be made in compliance with all applicable Federal and State laws and regulations. Note: direct customers (i.e., those that purchase primarily through wholesalers), see note C1 and C2 for additional credit information.

The address for returns is:

Pfizer Inc
Memphis Logistics Center
1855 E. Shelby Oaks Drive
Memphis, TN 38134
Attn: Returns Goods

All products must be returned freight prepaid by the sender, using generally accepted shipment methods. Use a separate packing list for each carton to ensure completion and customer credit. Upon receipt of the merchandise and verification of the contents and condition of the merchandise, a credit memorandum will be issued as appropriate. Credit will be issued at the lower of:

1. existing or contract price in effect 12 months prior, or
2. the current replacement price, or
3. original purchase price.

Partial bottles may be returned, and credit will be issued in 10% increments to a maximum of 70% for any opened package.

B. Merchandise delivered to Non-Returnable may be considered for exchange or credit (in full or partial) in the case of unusual circumstances. Prior approval is required by authorized Company personnel.

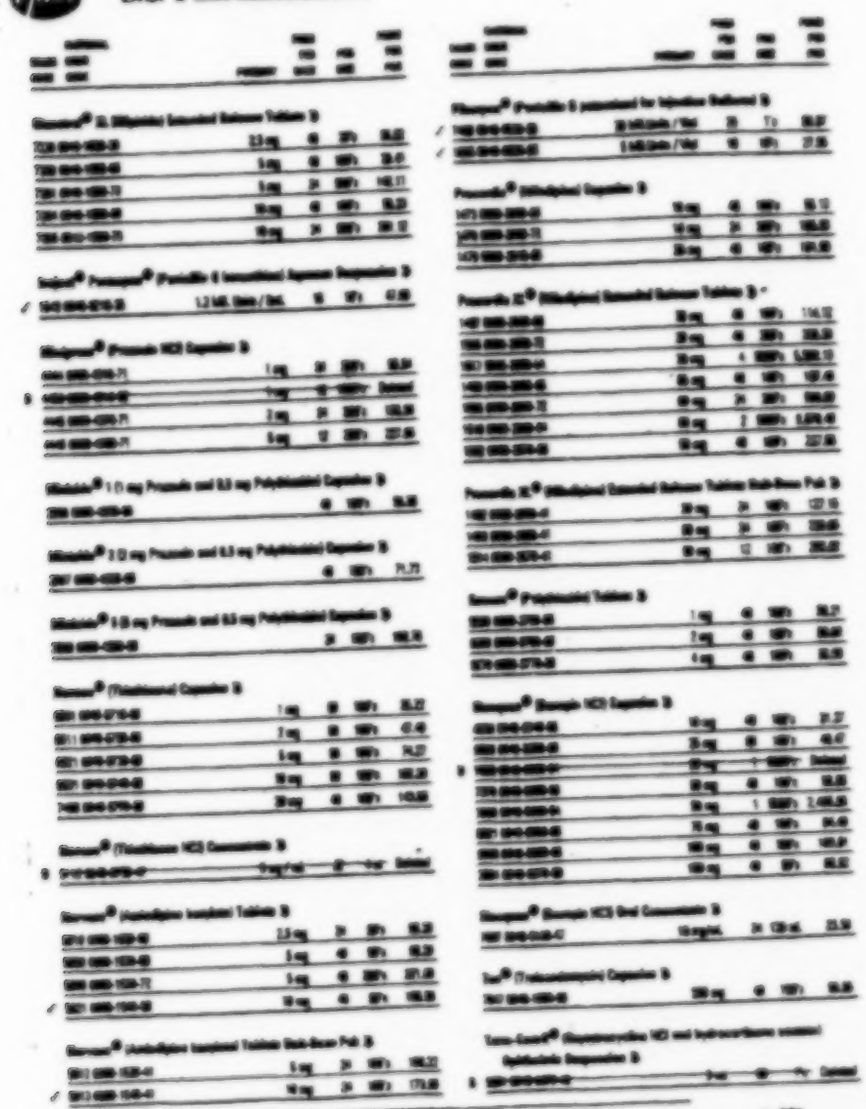
1. Customers with assigned Trade Development Managers should contact their Trade Development Manager.
2. All others should contact Customer Service at the aforementioned number listed above.

C. Additional information for specific types of customers:

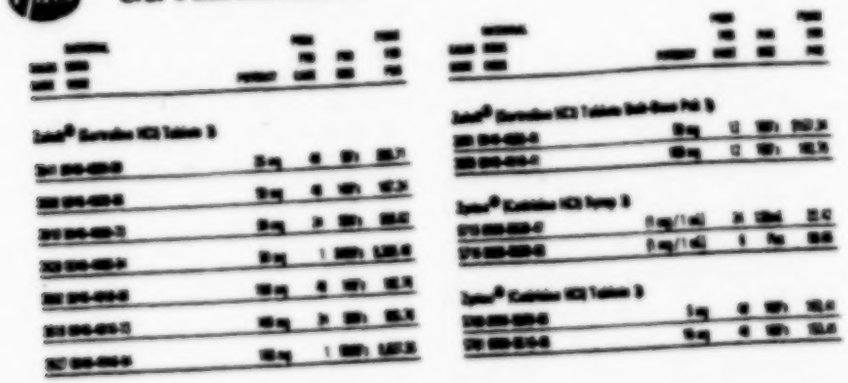
1. Hospitals, Clinics, Government Institutions, and other nonretail private entities: The Prescription Drug Marketing Act (PDMA) places specific restrictions on the return of pharmaceutical products from hospitals, healthcare entities and charitable institutions. The following applies to these entities to comply with the PDMA guidelines. If products were purchased from a wholesaler under a prime vendor contract, you may request that we issue a credit invoice to you through a specific wholesaler. If you choose this option, you must supply the following information with your request: your customer number, your hospital DEA number and/or HIN number, your buying group contribution memo, and the prime vendor wholesaler to receive credit. If product is were purchased at contract prices direct from Pfizer, then applicable credit will be issued to your direct account number, or to your preferred wholesaler if you supply the information requested above.

2. Non-Direct Retail Accounts: Customarily, returned goods are channeled through the source of purchase. However, returnable merchandise may be requested direct to Pfizer, and appropriate credit will be issued through your preferred wholesaler. In order to receive credit when returning merchandise, a non-direct account must list the merchandise being returned on a sheet of paper that identifies the pharmacy name, address and the desired wholesaler, name and address through which a credit invoice should be issued. Should no wholesaler be identified, Pfizer reserves the right to issue no credit. Pfizer cannot be responsible for the application of the credit from the wholesaler to the specific non-direct account.

U.S. Pharmaceuticals



U.S. Pharmaceuticals



Pfizer Pharmaceuticals Product Liability Protection Policy

In the event of a claim or lawsuit arising out of the dispensing of a Pfizer Pharmaceuticals product, it is Pfizer's policy to defend and hold harmless the pharmacist or the pharmacist's employer if the following conditions are met:

- If a prescription product, the prescription was properly filled by the pharmacist;
- the product was not improperly stored or packaged;
- there is no evidence of negligence or any improper or illegal act by the pharmacist or employer;
- the pharmacist has not made express warranties nor provided information inconsistent with the approved product labeling;
- the pharmacist and the pharmacist's employer, if any, provide Pfizer with prompt notice of the claim or lawsuit and fully cooperates with Pfizer in the defense of the claim or lawsuit.

Pfizer
235 East 42nd Street
New York, NY 10017

FIRST CLASS MAIL
U.S. POSTAGE
PAID
NEW YORK, NY
PERMIT NO.
4294

Pfizer U.S. Pharmaceuticals

Important Price Information

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA

Plaintiff,

v. Civil Action No. _____

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine

ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine

Defendants.

DECLARATION OF JUDITH L. TEMPEL
IN SUPPORT OF PLAINTIFF'S MOTION
FOR PRELIMINARY INJUNCTION

1. My name is Judith L. Tempel. From May 1, 2000 to present, I have served as the Manager of Distribution Operations of Eli Lilly and Company ("Lilly").

2. Lilly is a corporation organized and existing under the laws of Indiana that maintains its principal place of business in Indianapolis, Indiana.

3. I have been an employee with Lilly for nine (9) years serving in various roles prior to my current position. I received my Masters in Civil Engineering from Purdue University in Indiana in 1990.

4. I am filing this Declaration in support of Plaintiffs Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for

Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").

5. I am knowledgeable about Lilly's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Lilly's sales of prescription drugs in Maine.

6. All sales of Lilly's prescription drugs by Lilly occur outside Maine through direct, arms-length, transactions with authorized, independent wholesalers or distributors. Orders for all Lilly products from authorized wholesalers for distribution in the United States are filled for distribution from the Lilly warehouses located in Connecticut, Indiana and California. In accordance with the terms of Lilly's standard agreement with wholesalers ("Agreement"), the warehouse delivers the prescription drugs to the wholesalers or distributors on the loading dock of Lilly's warehouse. As is stated in the Agreement, title to the prescription drugs passes to the wholesaler or distributor upon delivery to the wholesaler or distributor at the Lilly warehouse. Wholesalers make payments for the prescriptions drugs purchased pursuant to the Agreement by electronic transfer to Lilly through Mellon Bank in Pittsburgh, Pennsylvania. Wholesalers and distributors sell the prescription drugs to their customers who are located throughout the country, including customers in the state of Maine, in separate, independent transactions. The wholesalers and distributors do not act on behalf of Lilly in the resale of the prescription drugs. From time to time, at the request of the wholesaler or distributor (or in the case of Lilly's growth hormone product, Humatrope®, the relevant health care facility or treating physician's office), Lilly may ship product directly to a particular end customer of a wholesaler or distributor, but the terms of the sale are governed by the same Agreement provisions, and the wholesaler or distributor are responsible for payment. Lilly's policy of selling its products in this manner has been in place for at least three (3) years.

7. On or about August 4, 2000, Lilly received the letter dated August 2, 2000 from Kevin W. Concannon, Commissioner of the State of Maine Department of Human Services, a true copy of which is attached to this declaration as Exhibit A.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August 9, 2000

/s/

Judith L. Tempel
Manager of Distribution Operations
Eli Lilly and Company

[Exhibit A]

Angus S. King, Jr.
Governor

Kevin W. Concannon
Commissioner

State Of Maine
DEPARTMENT OF HUMAN SERVICES
Augusta, Maine 04333

August 2, 2000

RICHARD L. BROWN, MC255
ELI LILLY AND COMPANY
LILLY CORPORATE CENTER

INDIANAPOLIS, IN 46285

Dear RICHARD L. BROWN, MC255,

I am writing to you on behalf of the State of Maine, Department of Human Services. I want to inform you about the new Maine Rx Program and invite you to participate in the rebate program for this initiative. I am enclosing a copy of the law, Public Law 1999, chapter 786, for your review.

The Governor and the Legislature passed this new law, during the past legislative session, which goes into effect on January 1, 2001. Under the Maine Rx program the State will serve as a pharmaceutical benefit manager (PBM) for the estimated 325,000 Maine residents who have no prescription drug benefit as part of a private or public health insurance program. Those residents would be eligible to receive a Maine Rx card.

The Maine Rx Program would provide your company's products to an ever growing population and a population that would exceed the current Medicaid population, which is currently 170,000 people. This means greater access to and utilization of your pharmaceuticals.

You will also find a rebate agreement enclosed. I am requesting you sign and return this agreement as soon as possible, but not later than November 1, 2000, so your company's products may be included in the Maine Rx Program for the January 1, 2001 start date. This law also addresses profiteering, unfair trade practices, and requires the Department impose prior authorization requirements in the Medicaid Program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers who do not enter into rebate agreements.

Also to be noted, the names of manufacturers and labelers who do not enter into rebate agreements pursuant to this law are public information. Your company has the opportunity to assist those Maine citizens with a real need for affordable prescription drugs. An added benefit to participating is your company gains nationwide recognition as a participant in the Maine Rx Program. This Program has received nationwide press attention and will continue to do so in the foreseeable future.

Thank you for your continued support of Maine Pharmacy Programs and for your concern for the prescription drug needs of all Maine citizens.

We look forward to working with you, and should you have any questions concerning this Program, feel free to call Jude Walsh, Director, Division of Quality Improvement at (207)287-1815 for our direct assistance.

Sincerely,

/s/
Kevin W. Conannon, Commissioner

Enclosures: PL 786
Rebate Agreement

MAINE RX PROGRAM REBATE AGREEMENT

BETWEEN

THE COMMISSIONER OF THE DEPARTMENT OF HUMAN SERVICES OF THE STATE OF MAINE

And

THE MANUFACTURER IDENTIFIED IN SECTION VIII

OF THIS AGREEMENT

(Hereinafter referred to as the "Manufacturer")

The Commissioner, on behalf of the State of Maine, and the Manufacturer, on its own behalf for the purposes of complying with Public Law 1999, chapter 786, hereby agree to the following:

I. DEFINITIONS

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified herein:

(a) "*AVERAGE WHOLESALE PRICE*" means the Wholesale Price charged on a specific commodity that is assigned by the drug Manufacturer and is listed in a nationally recognized drug-pricing file.

(b) "*CALENDAR QUARTER*" means four times a year. Specifically the first Calendar Quarter will be from January 1, 2001 — March 31, 2001. Each successive three-month period shall be a Calendar Quarter.

(c) "*COMMISSIONER*" means the Commissioner of the Department of Human Services.

(d) "*DEPARTMENT*" means the Department of Human Services.

(e) "*MANUFACTURER*" means the entity holding legal title or possession of the National Drug Code (NDC) for the Prescription Drug.

(f) "*NATIONAL DRUG CODE* (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this Agreement, the complete 11-digit NDC will be used including the labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or -formulation), and package size code to identify a prescription drug.

(g) "*NET SALES*" means Calendar Quarter gross sales revenue less cash discounts allowed and all other price reductions which reduce the actual price paid; and as discussed under the definition of WP.

(h) "*PRESCRIPTION DRUG*" means (1) legend drugs, defined as drugs carrying the statement "Caution: Federal Law Prohibits Dispensing Without A Prescription" and (2) any other drugs which by State law or regulation require the prescription of a licensed practitioner for dispensing. For purposes of this Agreement, all Prescription Drugs must be identified by the Manufacturer's labeler code segment of the National Drug Code (NDC).

(i) "*QUALIFIED RESIDENT*" means a resident of the State who has obtained from the Department a Maine Rx enrollment card.

(j) "*REBATE AMOUNT*" means the Medicaid Rebate amount.

(k) "*REBATE PAYMENT*" means, with respect to the Manufacturer's Prescription Drugs, the Calendar Quarter payment by the Manufacturer to the State of Maine

which shall be the sum of the Rebates of each prescription drug (computed for each dosage form and strength of each Prescription Drug) calculated as follows:

(1) The total number of Units paid under the Maine Rx Program for qualified residents during the Calendar Quarter multiplied by the Rebate amount per Unit.

(2) Effective January 1, 2001, a percentage equal to the Medicaid Rebate percentage to the State of Maine in effect for the corresponding time period.

(l) "*UNIT*" means drug Unit in the lowest identifiable amount (i.e. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the Unit for each dosage form and strength of each Prescription Drug in accordance with instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate program under Section 1927 of the Social Security Act.

(m) "*UTILIZATION DATA*" means the information regarding the total number of Units of each dosage form and strength of the Manufacturer's Prescription Drugs paid during the Calendar Quarter under the Program. Drugs dispensed prior to January 1, 2001 are excluded. The Utilization Data includes: (1) 11-digit NDC, including package size code; (2) product name; (3) quantity of Units paid during the Calendar Quarter by 11-digit NDC; (4) total number of prescriptions paid during the Calendar Quarter by 11-digit NDC; and (5) total dollar amount paid during the Calendar Quarter by 11-digit NDC.

(n) "*WHOLESALE PRICE* (WP)" means, with respect to a Prescription Drug of the Manufacturer for a Calendar Quarter the average price paid by Wholesalers in the United States to the Manufacturer, for ultimate

distribution to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to Wholesalers where the drug is relabeled under that distributor's national drug code). WP includes cash discounts allowed and all other price reductions, which reduce the actual price paid. It is calculated as a weighted average of prices for a Manufacturer's package sizes for each Prescription Drug by the Manufacturer during that Calendar Quarter. Specifically it is calculated as Net Sales divided by number of Units sold, excluding drugs or any other items given away but not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the Units of each drug sold under the bundled arrangement. The V/P for a Calendar Quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjusted the prices actually realized.

(o) "*WHOLESALER*" means any entity (including a pharmacy or chain of pharmacies) to which the Manufacturer sells the Prescription Drug, but that does not re-label or repackage the Prescription Drug.

II. MANUFACTURER'S RESPONSIBILITIES

The Manufacturer agrees to the following:

(a) To calculate and to make a Rebate Payment each Calendar Quarter to the State of Maine for the Manufacturer's Prescription Drugs paid for by the Department pursuant to the Maine Rx Program during a Calendar Quarter under the Maine Rx Program as follows:

Manufacturer's first rebate payment for the Calendar Quarter January 1, 2001 through March 31, 2001 shall be due September 30, 2001, or 30 days after receipt of

utilization data pursuant to Section III (a) of this Agreement, whichever is later.

All subsequent Rebate payments will be made by the Manufacturer to the State of Maine within 30 days of the close of each Calendar Quarter, or within 30 days upon receipt of the Utilization Data pursuant to Section III (a) of this Agreement, whichever is later. Simultaneously, with each Rebate Payment, the Manufacturer will provide the Department with the Manufacturer's most recent price catalog, unless no price changes were made from the previous Calendar Quarter.

(b) To continue to make a Rebate Payment to the State of Maine on all of its Prescription Drugs as defined in this Agreement so long as this Agreement, or a successor Agreement, is in force and as long as such Prescription Drugs are dispensed under the Manufacturer's NDC. If there are no sales by the Manufacturer during a Calendar Quarter the WP used for the most recent Calendar Quarter in which sales occurred will continue to be used in calculating Rebates.

(c) The Manufacturer will be responsible for Rebates on claims for prescription drugs that were dispensed within one year of the date that the claim was paid by the Department.

(d) The Manufacturer agrees to maintain all books, documents, papers, accounting records, and any other evidence pertaining to this Agreement and make such material available at its offices during normal business hours and shall send copies of such material to the Department upon the request of the Department during the period of this Agreement and for a period of two years after the termination of this Agreement. The Manufacturer shall allow inspection of pertinent documents by the Department or any authorized

representative of the State of Maine, and shall furnish copies thereof, if requested.

III. COMMISSIONER'S RIGHTS AND RESPONSIBILITIES

(a) The Department, on behalf of the Commissioner, shall send the Utilization Data as defined in this Agreement, to the Manufacturer, by certified mail, return receipt requested, within 60 days following the last day of each Calendar Quarter for qualified residents. The Commissioner, through the Department, shall maintain electronic claims records for the most recent four Calendar Quarters that will permit the Manufacturer to verify through an audit process The Utilization Data provided by the Department.

(b) The Department shall conduct audits, as it deems necessary to verify rebate calculation and payment.

IV. DISPUTE RESOLUTION FOR DISCREPANCIES IN REBATE AMOUNTS

Discrepancies in Rebate amounts must be resolved using the following process:

(a) If there is a discrepancy in the Manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the Manufacturer or labeler, the Department, at the Department's expense, may hire a mutually agreed-upon auditor. If a discrepancy still exists following the audit, the Manufacturer or labeler shall justify the reason for the discrepancy or make payment to the Department for any additional amount due.

(b) If there is a discrepancy against the interest of the Manufacturer or labeler in the information provided by the Department to the Manufacturer or labeler regarding the Manufacturer's or labeler's Rebate, the Manufacturer or labeler, at the Manufacturer's or labeler's expense,

may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the Department. If a discrepancy still exists following the audit, the Department shall justify the reason for the discrepancy or refund to the Manufacturer any excess payment made by the Manufacturer or labeler.

(c) Following the procedures established in paragraph a or b, either the Department or the Manufacturer or labeler may request a hearing before the Department of Human Services Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

(d) The Manufacturer further agrees that the sole and exclusive means for the presentation of any legal claim against the State arising out of this Agreement shall be in accordance with 5 MRSA section 11001. The Manufacturer further covenants not to initiate legal proceedings in any State or Federal court in addition to, or in lieu of, proceedings under section 11001. This Agreement shall be governed in all respects by the laws, statutes, and regulations of the United States of America and of the State of Maine. The Manufacturer consents to personal jurisdiction in the State of Maine.

(e) Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

V. CONFIDENTIALITY PROVISIONS

(a) Commercial or financial information disclosed by the Manufacturer in connection with this Agreement is confidential information, and will not be disclosed by the Commissioner or the Department (including any auditors or agents thereof) in a form which discloses the identity of a specific Manufacturer or Wholesaler, prices

charged for drugs by such Manufacturer or Wholesaler, in accordance with 42 U.S.C. § 1396r-8(b)(3)(D), 22 M.R.S.A. § 402(3) and Maine Rules of Evidence, Rule 507.

(b) The Manufacturer will guarantee the protection and confidentiality of the Utilization Date, including the proper care, custody, use and preservation of records, papers, files, communications of the Department and any other information that may reveal information related to the Utilization Data. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.

(c) Notwithstanding the non-renewal or termination of the Agreement for any reason, the confidentiality provisions will remain in full force and effect.

VI. TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an indefinite period beginning on January 1, 2001.

(b) The Manufacturer may terminate the Agreement for any reason, and such termination shall become effective the first day of the first Calendar Quarter period beginning sixty (60) days after the Manufacturer gives written notice requesting termination.

(c) The Commissioner may terminate the Agreement for any reason, upon sixty- (60) days prior written notice to the Manufacturer.

(d) The termination of this Agreement by either party will not affect any Rebate payments due to the State of Maine.

(e) In the event that any element of this Agreement is affected by a legislative amendment, including, but not limited to the percentage amount of Rebate required, such amended or revised provisions shall be incorporated by reference within this Agreement and shall supersede any of the conflicting provisions of this Agreement. If either party is unwilling to accept such a change in terms, this Agreement may be terminated pursuant to the terms set out in subsections (a) through (d) above.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Commissioner will be sent to:

Maine Rx Program
Director of Pharmacy Programs
Bureau of Medical Services, 3rd Floor
11 State House Station
Augusta, ME 04333-0011

Notice to the Manufacturer will be sent to the address provided to the Department by the Manufacturer.

(b) In the event of a transfer of ownership of the Manufacturer, this Agreement is automatically assigned to the new owner subject to the conditions specified in this Agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Commissioner under the Constitution, the Social Security Act, other Federal laws or State laws.

(e) The terms "Department" and "Manufacturer" incorporate any contractors or agents thereof, which fulfill responsibilities pursuant to this Agreement unless specifically provided for in the Rebate Agreement.

(f) This Agreement will not be altered except by an amendment in writing signed by both parties and except as indicated in subsection VI (e). No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by a duly appointed representative of the Manufacturer, and the Commissioner, and approved by the Office of the Attorney General.

(g) In the event that a due date falls on a weekend, or a Federal or State holiday, the report or other item will be due on the first business day following that weekend or holiday.

VIII. MANUFACTURER'S ACCEPTANCE

I, _____ hereby agree to the terms
(Name of Authorized Representative)
of this Agreement for the following Manufacturer(s) and labeler(s):

_____	_____
(Labeler Name)	(Code)
_____	_____
(Labeler Name)	(Code)
_____	_____
(Labeler Name)	(Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Signature) (Title)

Date: _____

IX. COMMISSIONER'S CERTIFICATION

This is to certify that _____ is a participant in the Maine Rx Program Rebate Program effective _____.

_____ _____

Christine Zukas-Lessard DATE: _____

Acting Director, Bureau of Medical Services
For the Commissioner

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH
AND MANUFACTURERS
OF AMERICA,

Plaintiff

v. Civil Action No. ___

KEVIN CONCANNON, in his official
Capacity as Commissioner of the
Department of Human Services for
the State of Maine, and
ANDREW KETTERER, in his official
Capacity as Attorney General
for the State of Maine,

Defendants

AFFIDAVIT OF SCOTT HOWELL, M.D.
IN SUPPORT OF PLAINTIFFS
MOTION FOR A PRELIMINARY INJUNCTION

1. My name is Dr. Scott Howell. I am Vice President of National Accounts, Managed Care, SmithKline Beechham Corporation. An accurate copy of my resume is attached as Exhibit A to this Affidavit.

2. When prior authorization is required for a drug under a plan providing prescription drug coverage, a physician must obtain specific permission from the plan each time the physician wishes to prescribe the drug, or the pharmacist must obtain specific permission from the plan each time he or she is asked to fill a prescription for the drug. The purpose of requiring prior authorization is to limit the use of the drug.

3. Prior authorization is often employed by managed care organizations ("MCOs") to enforce a drug formulary and is

usually intended to limit the drugs to be prescribed by health care professionals. MCOs typically require health care professionals to obtain prior authorization from the MCO before prescribing a drug (1) to ensure proper use of prescription drugs with a high potential for inappropriate use, (2) to limit the use of prescription drugs with severe or life threatening side effects and/or drug interactions; and (3) to encourage the use of cost-effective medications without diminishing safety or efficacy.

4. Prior authorization is not supposed to be, and on information and belief has never been, utilized as a form of punishment and without considering safety, efficacy and the availability of other drugs. On information and belief, prior authorization has never been required for a drug under one prescription drug coverage, for the purpose of influencing the manufacturer's pricing behavior in another program. On information and belief, such a use of prior authorization—limiting access to the drug by patients who are covered by one program, in order to bring about lower prices for the drug to patients who are covered in another program—is unprecedented. This, however, in my opinion, is the obvious aim, and would be the inevitable effect, of the Maine Act challenged in this case.

5. Even when justified by the considerations described in paragraph 3, prior authorization does not come without a cost to the healthcare professional and the patient. Consequently, it is my opinion that application of the prior authorization process for the artificial punitive purpose contemplated by the Maine Act—unrelated to Medicaid patient care or even the administration of the Medicaid program—will impose significant and gratuitous burdens on Medicaid healthcare providers and patients, as a result of which those patients likely will not receive the safest and most efficacious drugs that they would otherwise receive. Unmoored from the considerations described in paragraph 3, it is my opinion that such prior authorization process will (1) lead to inappropriate

prescribing of medications for Medicaid patients, (2) needlessly burden doctors who treat Medicaid patients; and (3) cause unnecessary inconvenience for Medicaid patients.

6. In my opinion, prior authorization of drugs, without regard to safety or efficacy, will lead to drugs being prescribed that are less safe and efficacious. Healthcare professionals choose medicines for patients based on their understanding of their patients' needs and the efficacy and safety profile of the drugs. Prior authorization causes doctors to switch from first-choice drugs to potentially less safe and effective second-choice drugs. Even though healthcare professionals would not knowingly prescribe another drug that they expected to be ineffective or harmful to the patient, healthcare professionals would be forced to switch to drugs that have safety and efficacy profiles with which they are less familiar or may consider less desirable.

7. Suppose, for example, that, pursuant to the Maine Act, physicians in Maine were restricted from prescribing *Augmentin* for their Medicaid patients. *Augmentin*, a leading antibiotic used for ear infections in children, was recommended in national guidelines published by the CDC for such use. Less effective alternatives do exist, and if *Augmentin* were subject to prior authorization, then it is likely that Maine healthcare professionals would switch patients to these less effective drugs. They would do so believing in good faith that the patient will be cured. However, this will not be the case in some instances. Some patients will have resistant infections that withstood the less effective product; some will recover more slowly; and others will suffer complications needlessly.

8. An inappropriate implementation of prior authorization also needlessly burdens the healthcare professional. When physicians decide based upon their professional judgment that a drug, which is subject to prior authorization, is the best remedy for their patients, the physicians are required each time they choose to prescribe the drug to justify to the MCO

why that particular patient needs the drug and then to obtain the MCO's approval for that use. In this day of increasing burdens in healthcare, it is no small measure to unnecessarily add to the hassles of doctors. In fact, it harms them greatly and reduces time they can spend with their patients.

9. Such broad prior authorizations cause unnecessary hassles and anxiety for patients. In many instances, patients cannot immediately receive their prescriptions subject to this process. Patients many times are required to wait until the MCO approves it and must return to the pharmacy to retrieve the drugs if they are approved. Frequently, anxiety and confusion occurs with patients because they do not understand why the medicine their doctor chose for them has not been approved and requires a switch. This anxiety can be exacerbated in situations where the patient had used the drug previously. This, in turn, can lead to compliance problems for patients.

10. When prior authorizations are implemented properly, they can increase the clinical and cost-effectiveness of a drug formulary. When used wrongly, they cause harm to both patients and health professionals. Because of these sensitive factors, MCO's do not implement blanket prior authorizations without regard to safety, efficacy, and cost-effectiveness of the drugs. MCOs hire large pharmacy departments, convene formal committees with healthcare professionals, and seek outside expert advice to make such important decisions. The implementation of prior authorization under the Maine Act, by contrast, does not permit such a thoughtful process. Consequently, in my opinion, this will create a high likelihood that it will cause harm to patients and healthcare professionals.

11. Requiring prior authorization for SmithKline's drugs in the Medicaid program in Maine is likely to have an adverse effect on SmithKline's market share and sales beyond the Medicaid program. When physicians encounter an obstacle (such as prior authorization) to prescribing a drug under one

program or plan, the existence of that obstacle tends to discourage them from prescribing the drug even under programs or plans that do not impose such obstacles. Thus, for example, in our experience, the most restrictive formularies in an area become de facto formularies for the area generally. For that reason, the Maine Act would curtail access to SmithKline's drugs not only for Maine residents covered by the Medicaid program but for the general population of Maine covered by the Maine Rx Program, causing a correspondingly greater loss to SmithKline of market share and sales for the prior authorized drugs.

12. The foregoing is based on personal knowledge, other than that which is upon information and belief as described above.

I state under penalty of perjury that the foregoing is true and correct. Executed on August 9, 2000.

/s/
SCOTT HOWELL, M.D.

[Exhibit A]

HOWARD SCOTT HOWELL, MD, MBA

Home	861 Lesley Road Villanova, PA 19085 (610) 989-0949
Office	3FP0505, Three Franklin Plaza Philadelphia, PA 19101 (215) 751-7549
Personal	DOB: December 13, 1960 Married, one child

Education

Undergraduate Education 1979-1983	The University of Notre Dame B.S. with high honors Pre-professional Studies
Medical Education 1983-1987	The Ohio State University M.D. magna cum laude
Internship and Residency 1987-1990	The Duke University Medical Center Internal Medicine
Graduate Education 1994-1996	The Fuqua School of Business Duke University M.B.A., Fuqua Scholar
Board Certification	Internal Medicine
Licensure	Ohio

Work History

1997-Present	SmithKline Beecham Pharmaceuticals Philadelphia, Pennsylvania Director/Vice President, Managed Care Division
1993-1997	The Ohio State University Medical Center Columbus, Ohio Medical Director of Ambulatory Care
1990-1993	Henderson County Internists Hendersonville, North Carolina Private Practice, General Internal Medicine

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff,

v.

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine

ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine

Defendants.

Civil Action No. _____

AFFIDAVIT OF DAVID MOULES
IN SUPPORT OF PLAINTIFF'S
MOTION FOR A PRELIMINARY INJUNCTION

1. My name is David Moules. I am Vice President and Director, National Accounts, Managed Care Division, SmithKline Beecham Pharmaceuticals ("SmithKline"). I have responsibility for SmithKline's national account customers in Health Maintenance Organization, Pharmacy Benefit Manager, Institutional (Hospital/GPO, Long Term Care), and Federal Accounts business segments. An accurate copy of my resume is attached as Exhibit A to this Affidavit.

2. SmithKline manufacturers and markets pharmaceuticals, vaccines, over-the-counter medicines and health related consumer products. One of the world's leading healthcare companies, SmithKline employs 47,300 people worldwide with operations in 160 countries.

3. I am knowledgeable about SmithKline's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically the extent to which SmithKline sells its drugs in Maine.

4. Although drugs produced by SmithKline are sold in Maine, SmithKline itself does not sell any of its drugs in Maine. (SmithKline sells vaccines in Maine, but it is my understanding that these vaccines are not covered by the Maine statute at issue in this case. SmithKline also sells to federal facilities in Maine under the Federal Supply Schedule.) SmithKline sells its drugs to wholesalers/ distributors, which are independent companies in which SmithKline has no ownership or other financial interest. None of these wholesalers/distributors is headquartered in Maine, and none of them maintains any warehouses in Maine to which SmithKline currently ships any of its drugs. SmithKline instead sells its drugs to these wholesalers/ distributors in transactions in which the sale does not take place in Maine, but at locations outside of Maine where SmithKline delivers its drugs to common carriers that transport the drugs to the wholesalers'/distributors' Out of state warehouse.

5. Under the governing Wholesaler Distribution Agreement, an example of which is attached as Exhibit B to this affidavit, title passes from SmithKline to the wholesaler upon SmithKline' s delivery of the drug to the common carrier at SmithKline's Tennessee distribution facility. In accordance with the terms of the Agreement, the warehouse then ships the order via common carrier (*i.e.*, Roadway Express, Federal Express, UPS) to the wholesaler or

distributor at a location outside the state of Maine. Although SmithKline will replace drugs lost or damaged during shipment, once the drug is delivered, the risk of loss passes to the wholesaler or distributor at its delivery site outside of Maine.

6. The SmithKline warehouse located in Knoxville, Tennessee fills electronic orders from wholesalers and distributors. SmithKline does not earmark its drugs for sale in particular states. To the contrary, under the terms of the Agreement, the wholesaler is free to sell drugs it has purchased from SmithKline to any customer (*e.g.*, a retail pharmacy) located anywhere in the country. Wholesalers and distributors sell the drugs to their customers who are located throughout the country, including customers in the state of Maine. The wholesaler/distributor does not act on behalf of SmithKline in the distribution chain.

7. I am also knowledgeable about the impact that prior authorization has on SmithKline's market share and sales. It is my opinion that the Maine Act threatens drug manufacturers with prior authorization in the Medicaid program if they decline to enter into rebate agreements with the state under Maine Act, precisely because the proponents of the statute understand that prior authorization severely and perhaps permanently damages a drug's market share and sales, and that, from a manufacturer's standpoint, avoiding prior authorization would therefore be a powerful incentive to enter into rebate agreements with the state.

8. The purpose of requiring prior authorization is to limit the use of the drug. When a drug is subject to prior authorization under a plan or program providing prescription drug coverage, each time a physician prescribes the drug for a patient, the physician is required to justify doing so to the administrator of the plan or program, and the prescription will not be covered under the plan or program without the administrator's approval. The circumstance under which

prior authorization is typically required are described in the Affidavit of Dr. Scott Howell.

9. As four examples demonstrate, requiring prior authorization with respect to a manufacturer's drug severely curtails patient access to the drug and sharply reduces the drug's market share and sales as the prior authorization shifts patients to competing drugs of other manufacturers that are not subject to prior authorization.

10. *Augmentin*. Augmentin is SmithKline's flagship antibiotic product, indicated for the treatment of infections caused by susceptible strains of bacteria in conditions such as lower respiratory tract infections, otitis media, sinusitis, skin and skin structure infections, and urinary tract infections. Patient access to Augmentin was sharply curtailed in the Las Vegas, NV market, and Augmentin sales in that market sharply dropped, when a prior authorization was put in place by the largest managed care organization in the metropolitan statistical area (over 100,000 lives). When the prior authorization was imposed in the first quarter of 1999, Augmentin had a 49% market share. Its market share two quarters after the PA was implemented was 18%. The prior authorization thus resulted in a 60.9% loss in market share.. Since implementation of the prior authorization, market share and sales have been significantly reduced and have not recovered. As a result of the prior authorization, SmithKline's cumulative loss in sales revenue at this health plan for the first full quarter in which the prior authorization was in effect was approximately $272,000. *See* Exhibit C to this Affidavit.

11. *Paxil*. Paxil, another SmithKline product, is a selective seratonin reuptake inhibitor ("SSRI"), indicated for the treatment of depression, obsessive compulsive disorder, panic disorder, and social anxiety disorder. Patient access to Paxil was reduced, and Paxil market share and sales correspondingly fell, in numerous geographical areas when a prior authorization was imposed by a large national managed

care organization in the first quarter of 1997. When the prior authorization was imposed in the first quarter of 1997, Paxil had a 21% market share. Its market share two years later was 12%. The prior authorization thus resulted in a 41.8% loss of market share over the following eight quarters. As a result of PA, SmithKline's cumulative loss in sales revenue at this managed care organization over the eight quarters analyzed was approximately $7 million. See Exhibit D. Only after this customer merged with another company and the prior authorization was removed in the third quarter of 1999 did sales in those geographical areas begin to recover.

12. *Relafen*. Relafen is SmithKline's nonsteroidal anti-inflammatory drug product ("NSAID") indicated for acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis. Patient access to Relafen was reduced, and Relafen's market share and sales correspondingly fell, in numerous geographies when a prior authorization was introduced by a large national managed care organization in the first quarter of 1998. When the prior authorization was imposed in the first quarter of 1998, Relafen had a 12.8% market share. Its market share two years later was 4.2%. The prior authorization resulted in a 67.2% loss of market share over the eight quarters after the time the prior authorization was implemented. Since implementation of the PA, sales and market share have been significantly reduced and have not recovered. As a result of the PA, SmithKline's cumulative loss in sales revenue at this managed care organization over the eight quarters analyzed was approximately $2.9 million. *See* Exhibit E.

13. *Avandia*. Avandia is SmithKline's oral antidiabetic product indicated for gylcemic control in patients with type 2 diabetes. Patient access to Avandia was reduced, and Avandia market share and sales correspondingly fell, when a prior authorization was implemented by a large managed care plan in March 2000. The prior authorization resulted in a

drop in market share of 46% just two months after the prior authorization was implemented. *See* Exhibit F.

14. It is SmithKline's experience that the injury caused by a prior authorization can linger even after the prior authorization is lifted. Market share, once lost, is difficult to recover and may never be recovered, as physicians and patients develop loyalty to competing drugs of other manufacturers not subject to the prior authorization while the prior authorization on the manufacturer's drug is in place. The result for the manufacturer whose drug is subject to the prior authorization may be a permanent loss of sales and market share and a permanent loss of good will.

I state under penalty of perjury that the foregoing is true and correct. Executed on August 9, 2000.

/s/
DAVID MOULES

[Exhibit A]

DAVID A. MOULES

PROFESSIONAL EXPERIENCE

SMITHKLINE BEECHAM
U.S. PHARMCEUTICALS – MANAGED CARE DIVISION:
April 1997 – Present

Vice President and Director, National Accounts

Member of the Managed Care Division leadership team with responsibility for the national account customers in the HMO, PBM, Institutional (Hospital/GPO, Long Term Care) and Federal Accounts business segments. Primary responsibilities include:

- Provide strategic direction for the "business segments" that are responsible for selling/servicing the National Account customers of SB Pharmaceuticals.
- Develop and implement strategies to achieve sales (gross and net) objectives.
- Oversee the development, implementation and execution of marketing/business plans for the National Account Business Segments.
- Collaborate with SB Pharmaceutical groups (Sales, Marketing, Contract Management, Medical Affairs, Legal, etc.) to ensure the development and delivery of contracts, programs, and services which meet customer needs and enhance customer relationships.
- Forecast, plan and develop business plan objectives and budgets.
- SB Pharmaceuticals "Senior Management" contact/liaison for National Account customers in the IMO, PBM, Institutional and Federal Accounts business segments.

- Recommend most appropriate organizational/operating policies and strategies to achieve desired results.
- Evaluate/approve contracting strategies designed to improve business segment sales and profitability results.
- Assist in the negotiation of key customer proposals and contract renewals.
- Facilitate the development of Managed Care National Accounts personnel by establishing and monitoring Major Business Objectives (MBO's) for each direct report (for performance and personal development).

SMITHKLINE BEECHAM
DIVERSIFIED PHARMACEUTICAL SERVICES: September 1994 – April 1997

Senior Vice President

Member of Diversified's Executive Management Team responsible for the strategic planning and overall management of existing and potential managed care (HMO) and non-managed care (e.g., employer, TPA, insurance, consumer) clients. Primary responsibilities included:

- Managing the sales process to meet new business and client retention objectives
- Implementing a sales organizational structure that allowed Diversified to meet business objectives
- Recruiting/training and managing a national sales organization
- Managing the financial aspects of the business to improve profitability

CIGNA HEAL THCARE: June 1987- September 1994

Sales Vice President: April 1992 - September 1994

Responsible for recruiting, training, and motivating a high performance sales force in order to achieve Division results in

revenue growth, profitability, membership growth, persistency and new firm growth. In addition, the position responsibilities included assisting in key sale opportunities; maintaining executive level contacts with customers and producers; developing and monitoring annual sales plans; analyzing competitive information and providing input on local market needs; executing the human resource management process; preparing budget and staffing plans; and, maintaining relationships with matrix partners.

Sales Director February 1991 - March 1992

In reporting to the Sales Vice President, I was responsible for the hiring, coaching, and training of sales representatives and other office staff. As a Sales Director in a District office, I had full responsibility for developing annual sales plans; overseeing the management of the book of business; executing the human resource management process; preparing and monitoring the budget and staffing plans; assisting in key sales situations; and, coordinating sales/service plans with matrix partners.

Group Marketing Executive: June 1987 - January 1991

Responsible for employee benefit sales and account management for medical, dental, disability and life insurance lines of business. In this role, I managed an existing book of business in excess of $50 million in premium revenue; and was responsible for broadening the base of business through sales of both existing accounts as well as new firms. In addition, I was accountable for developing relationships for CIGNA within the employee benefits brokerage/consulting community.

[Exhibit B]

SB
SmithKline Beecham
Pharmaceuticals

WHOLESALER DISTRIBUTION AGREEMENT

Agreement January 1, 1999, between SmithKline Beecham Pharmaceuticals, a division of SmithKline Beecham Corpcration (SB), Philadelphia, Pennsylvania 19101, and

_____ Company _____

including its branches referred to on the attached Exhibit A, with main offices located at

_____

WHOLESALER.

Pursuant to this Agreement, SB appoints WHOLESALER as a distributor for its selected pharmaceutical products. The parties hereto, intending to be legally bound, hereby agree as follows:

I. OBLIGATIONS OF SB:

A. Shipment and Pricing to WHOLESALER

SB shall sell to WHOLESALER and shall ship selected products to the above address and to addresses specified in Exhibit A, attached hereto and incorporated by reference. SB shall charge WHOLESALER for SB products in accordance with the WHOLESALER prices and policies shown itT the SB Wholesaler Price List plus all applicable Federal and State Taxes in effect on the date of SB's receict of order.

B. Special Contract Pricing

SB shall adjust the Net Wholesale Purchase Prices for SB products sold and shipped from WHOLESALER'S inventory under contract sales for which SB is the sole marketer and has provided Special Contract Prices to customers. Such adjustments shall be made in accordance with SB contract Policy and Procedure document SB's Contract Policies and Procedures attached to this Agreement as Addendum I and incorporated by reference.

C. Terms

Payment by Check

SB shall provide a cash discount of 2% off SB's invoices (~~after deduction of all SB authorized credit memos excluding tax and chargeback credit memos~~) for cash payments postmarked and mailed to SB no later than thirty (30) days from date of invoice. In the case of automatic shipments, SB shall provide a 2% cash discount when payment is postmarked and mailed within the time period specified on the invoice.

Payments by EFT (Electronic Funds Transfer)

SB shall provide a discount of 2% off SB's invoices (~~after deduction of all SB authorized credit memos excluding tax and chargeback credit memos~~) for electronic funds transfer value received no later than thirry-four (34) days (invoice terms, plus 4 days) from the date of invoice. In the case of automatic shipments, SB shall provide a 2% cash discount when payment is received within the time period specified on the invoice, plus 4 days.

D. Transportation Charge Prepayment

SB shall prepay all transportation charges on orders when routing is done at SB's discretion. If WHOLESALER requests special routing and SB approves of the routing which results in higher transportation cost than would be incurred as a result of the routing of SB's choice, then the difference in the transportation cost shall be borne by WHOLESALER.

E. Returns

SB shall accept for credit any SB products returned from WHOLESALER'S inventory. Returns of WHOLESALER'S stock will be credited at the price when purchased. In accordance with SB's existing practices, authorized credits for returns are subject to a 2% reduction for discounts taken from the original invoice price. (See Sections I(C) and II(A) for application of credits.) Except for returns resulting from shipping and/or ordering errors, SB will not accept any opened or unopened package returns taken back by the WHOLESALER from its customers. Freight charges that are a result of returns are the responsibility of the WHOLE-SALER. Furthermore, SB will not accept merchandise that has been altered by repackaging. All returns over $10,000 require prior approval by the SB Trade Account Manager or the Customer Satisfaction Consultant at 1-800-877-1158.

F. Product Recalls

SB shall compensate WHOLESALER for the expense incurred in performing all requested recall services. Such compensation Shall be limited to expenses incurred for recall services directly related to WHOLESALER'S inventory in WHOLE-

SALERS possession unless SB requests additional recall services in writing from WHOLESALER.

G. Product Liability Protection

SB shall guarantee that all SB products meet standards of identity, strength. quality and purity in their manufacture. If a claim is made against the WHOLESALER as a result of distributing an SB product. SB will, subject to the following conditions, provide legal defense—including the payment of all reasonable expenses and attorney fees—and assume any judgment liability. This guarantee is conditioned on SB being promptly notified of any claim, or the service of any complaint, and the full cooperation of the WHOLESALER, including complete access to all relevant records.

This protection does not apply if the claim results from any negligent, improper or illegal act, or failure to act on the part of the WHOLESALER, or if the Product had been repackaged or had not been properly stored, handled or distributed.

II. OBLIGATIONS OF WHOLESALER:

A. Payment for Products

WHOLESALER shall pay for all regular orders purchased by WHOLESALER, with payment to be received by SB no later than thirty (30) days for cash payments or thirty-four (34) days for EFT payments from the date of invoice, or in the case of automatic shipments or other extended billing purchases, within the terms specified on the invoice, plus four (4) days for EFT. As provided in I(C) above, SB will provide a 2% cash discount off SB's invoices (~~after deduction of selected credit memos described in the SB WHOLESALER Price List~~) for

cash payment received thirty (30) days and EFT payments received by thirty-four (34) days after date of invoice. In the case of automatic shipment purchased, SB will provide a 2% cash discount for payment received within the time period specified on the invoice statement, plus four (4) days for EFT. *All invoices must be paid in full under the terms specified above and no deductions, other than the cash discount, are permitted from SB invoices unless authorized by a prior credit memo.* Any late payments SB receives shall accrue interest at the maximum rate allowed by law.

B. Financial and Credit Position

WHOLESALER shall maintain an adequate financial condition satisfactory to SB and substantiate such a condition with audited financial statements or as otherwise requested by SB. If, in SB's judgment, at anytime before shipment, the financial condition of the WHOLESALER becomes impaired or unsatisfactory to SB, SB may require cash payment or appropriate security before shipment. If WHOLESALER experiences any event that adversely impacts its financial condition, including, for instance and without limitation, a loss of a significant contract, a write-off of a significant receivable or any event impacting 3% or more of WHOLESALER's revenues, net profits or working capital, WHOLESALER shall provide SB with written notice of such change in financial condition within 24 hours of its occurrence.

C. Payment of Unearned Cash Discounts

WHOLESALER shall reimburse SB for any cash discounts taken but not earned. SB will issue a second invoice for the Unearned Cash Discount for

which WHOLESALER shall make payment upon receipt of invoice.

D. Ordering

1. WHOLESALER shall transmit SB orders either direct or, if indirect, via Informatics Ordernet Clearinghouse, using the SB automated order entry system.

2. WHOLESALER shall place orders as follows:

   a. Not more than ~~four (4)~~ one stock orders transmitted within each ~~month~~ week, unless otherwise approved by SB in Philadelphia. Drop-shipments will be handled on an individual basis and must be approved by SB;

   b. Unlimited orders for new selected products, strengths or sizes (referred to below as new SB items) which WHOLESALER places during the first sixty (60) days after their introduction:

   c. Telephone orders only in emergencies, and limited to ten (10) line items with a limit of one case per line item. WHOLESALER will pay a charge of $35.00 for emergency orders; this charge will not apply to orders due to SB out-of-stock situation.

E. Inventory

1. WHOLESALER shall purchase exclusively from SB or an authorized distribution of SB or an authorized distributor of SB all requirements of SB products and maintain at all times an inventory of those SB MUST STOCK items designated in SB's then current Wholesale Price List, at such a level that WHOLE-SALER'S

total out-of-stocks for such line items will not exceed six (6) in any month. Intra-company transfers between distribution centers are allowable.

2. SB can request, at any time, information regarding inventory levels of any SB product. This information can be compiled from either computer records or actual physical inventory count by an authorized SB representative.

3. SB requires that WHOLESALER shall report as soon as reasonably possible their sales of SB products to IMS Health (DDD).

F. Services

1. WHOLESALER shall provide aggressive sales support for SB Products as well as the order-taking, question-answering and delivery services necessary to meet reasonable needs of customers for these products.

2. WHOLESALER shall credit applicable WHOLESALER Customers for products returned directly to SB by WHOLESALER'S customers for which SB has issued a return goods credit memo to WHOLESALER.

3. WHOLESALER shall provide prompt marketing and stocking of new SB items for customers.

G. Special Contract Pricing

1. WHOLESALER shall hold in confidence and not disclose, directly or indirectly, to any third party (other than the entity soliciting such quotations), any information concerning any Special Contract Prices quoted by either WHOLESALER or SB in bidding for a contract

sale, so long as a product award has not been issued by the party soliciting such quotations. (As in the case of any material breach, a violation of this provision shall constitute grounds for immediate termination as an SB distributor.)

2. WHOLESALER shall comply with the SB contracts SB's Contracts Policies and Procedures attached to this Agreement as Addendum I.

3. WHOLESALER shall provide SB with electronic chargeback owed to the WHOLESALER at the end of each week, month or quarter. SB will credit the WHOLESALER for such chargeback.

4. See attached insert.

H. Lawful Handling

1. With respect to SB products, WHOLESALER shall take such precautions as are necessary to prevent them from falling into the hands of those who may not lawfully possess or handle them, and fully comply with local, state and federal laws.

2. WHOLESALER shall maintain all federal, state and local registrations necessary for the lawful handling of all SB products and immediately notify SB of any denial, revocation or suspension of any such registration or any changes in the SB products which WHOLESALER is authorized to distribute.

3. WHOLESALER shall immediately report to SB any in-transit loss or shortage of SB products including controlled substances.

4. WHOLESALER shall report any administrative, civil or criminal action by local, state or federal authorities against WHOLESALER, its officers or employees, regarding alleged violations of the Controlled Substance Act of 1970, as amended or other comparable legislation, and shall provide SB with complete information concerning the disposition of such action.

I. Proper Handling and Storage

WHOLESALER shall handle and store SB products in a clean and orderly location and in a manner that will assure that the proper rotation and quality of such products are maintained. WHOLESALER shall comply with SB criteria on shipping products that require special handling. WHOLESALER shall allow SB to conduct a physical inspection of WHOLESALER's storage facilities at any time SB requests.

J. Substitution

WHOLESALER shall fill orders for SB products, only with SB products. WHOLESALER shall not substitute any orders for SB Products with product not manufactured by SB.

K. Transfer of Ownership—Change in Address

WHOLESALER shall notify SB of the terms and conditions of any transfer in majority ownership or control, or any change in address, at least thirty (30) days prior to such action.

L. Automatic Shipments

WHOLESALER shall accept automatic shipments of reasonable quantities of new SB items including those distributed on an extended billing basis. SB

reserves the right to determine the size of such shipments.

M. Claims

WHOLESALER shall report all claims within fourteen (14) days of the receiving date. Proper documentation must accompany the claim. Deductions on damaged goods, shortages or shipping errors will not be allowed. SB will issue credit to the WHOLESALER. Unless SB fails to provide credit within 30 days of notification by WHOLESALER.

N. Audit or Review and Payment of Prior Transactions

WHOLESALER must submit all requests for review or payment of prior transactions within twelve (12) months of the transaction date.

III. GENERAL PROVISIONS

A. All orders are subject to acceptance and approval by SB at its central Distribution Office in Philadelphia, Pennsylvania.

B. This Agreement may be terminated by either party immediately upon any material breach of the terms of this Agreement by the other.

C. Neither SB nor WHOLESALER shall be liable to the other for failing to do as agreed where such failure is the result of a strike or other labor disturbance, fire, flood, earthquake, storm, governmental action, or other reason beyond its control.

D. The relationship created by this Agreement is a buyer-seller relationship and not an agency relationship.

E. Title to products shipped to WHOLESALER will pass when delivered by SB to carrier.

F. In the event there is a shortage of any SB product, SB shall have the right to prorate such product among its WHOLESALERS in such a manner as it, in its sole discretion, deems to be in the public interest.

G. SB reserves the right to fill only as much of a WHOLESALER'S product order as SB, in its sole discretion (after conferring in, good faith with WHOLESALER), determines represents WHOLESALERS bona fide current requirements for such product, and SB may exercise such right whether or not it has announced a forthcoming price increase for such product.

H. This Agreement shall not be construed as limiting WHOLESALERS lawful right to choose such customers and charge such prices as WHOLESALER freely determines or as granting to WHOLESALER exclusive rights in any territory.

I. This Agreement may be changed or amended only in writing signed by duly authorized representatives of SB and WHOLESALER, and in the case of SB, only by a representative from its office in Philadelphia. All attachments and addenda to this Agreement are hereby incorporated by reference.

J. This Agreement shall not be assigned or otherwise transferred without SB's prior written consent.

K. This Agreement shall terminate automatically on December 31, 2000, or at any subsequent date specified in writing by SB. During its term, the Agreement may be terminated by either party on thirty days' written notice mailed to the other at the address set forth above.

L. Payment for SB products shipped but not invoiced at the time termination of this Agreement becomes effective and any outstanding invoices or advance chargeback credits shall become due immediately upon termination.

M. This Agreement supersedes all prior contracts. agreements and understandings between SB and WHOLESALER.

N. This Agreement shall be construed in accordance with, and governed by, the laws of the Commonwealth of Pennsylvania.

O. Terms of this Agreement apply to those distribution centers located in the Continential United States. Alaska and Hawaii.

P. Unauthorized deductions are in violation of this Agreement and will result in delayed shipments.

Q. During the term of this Agreement and for a period of one year thereafter, WHOLESALER shall maintain documentation of all sales of SB products, including documentation of the purchaser of such products and WHOLESALER's payment to SB for such products (together, the "Documentation"). SB shall have the right, upon reasonable prior written notice to WHOLESALER, to audit all Documentation at WHOLESALER's primary place of business during normal working hours for purposes of assuring the appropriateness of any and all payments made or reimbursement claimed and/or paid under this Agreement and to assess WHOLESALER's performance under this Agreement, and shall have the right to audit the systems and processes used by WHOLESALER to assure that sales and calculations are performed accurately in accordance with the terms of this Agreement. SB

agrees that such audits will only be conducted by SB employees or an authorized representative.

R. WHOLESALER represents and warrants that, to the best of its information and belief that the computer hardware and software systems used by WHOLESALER in supplying orders or other information to SB pursuant to this Agreement are, or shall be by ~~May~~ June 1, 1999, Year 2000 compliant, and that the continuity and quality of supply of orders or other information to SB will not be affected by the failure of WHOLESALER's systems due to any Year 2000 non-compliance. WHOLESALER shall provide any required additions or modifications to the design and performance specifications of WHOLESALER to ensure compliance with this warranty at no cost to SB. In addition to any other rights or remedies available to SB under this Agreement, WHOLESALER's obligation and SB's remedy for any breach of this warranty, or upon notification by WHOLESALER that the WHOLESALER's internal systems shall not be Year 2000 compliant by the date specified in this warranty, shall be, at SB's discretion, one or more of the following: 1) WHOLESALER shall take all reasonable steps to minimize the impact of any Year 2000 non-compliance by the WHOLESALER's internal systems on the continuity and quality of supply of orders or other information to SB, and shall afford SB at least equal priority with WHOLESALER's other preferred customers in maintaining the continuity and quality of supply of orders or other information to SB; 2) WHOLESALER shall make any necessary repairs or replacements to WHOLESALER's internal systems in order to correct the breach within 30 days of receiving written notice from SB to do the same; 3)

SB may revise or restrict WHOLESALER's credit line or require cash payment or appropriate security before shipment; and/or 4) SB may terminate this Agreement.

S. Nothing in this Agreement or the conditions of sale of product to WHOLESALER shall be construed as granting or implying the grant of any license under any patent or trademark rights or any other industrial property rights held by SB or any of its affiliates anywhere in the world outside of the U.S., and SB shall be entitled to exercise such patent or trademark rights and/or other industrial property rights to the fullest extent legally permissible at the time of such exercise. Unless authorized, no trademarks of which SB or any of its affiliates are proprietors or authorized users shall be applied to any goods originally supplied by them on removal from their original container except by a Pharmacist in the course of dispensing a prescription endorsed by a qualified medical practitioner to indicate the name of the product on the container, or by a medical practitioner dispensing their own prescriptions. In the case where a trademark was on the goods when originally supplied by them, this trademark shall not be altered, partly removed or partly obliterated. All subsequent purchasers shall be put on notice of these reservations and shall be required to put any further subsequent purchasers on like notice. In the case where trademark was [illegible] the goods when originally supplied by the WHOLESALER SB agrees to provide legal defense—including the payment of all expenses and attorney fees—and assume any liability for judgement based on any alleged breach of any such patent or trademark rights by WHOLESALER.

IN WITNESS WHEREOF, the parties hereto have executed this WHOLESALER DISTRIBUTION AGREEMENT as of the date set forth above.

WHOLESALER	SMITHKLINE BEECHAM PHARMACEUTICALS Division of SmithKline Beecham Corporation Philadelphia, Pennsylvania
/s/	/s/
By _____ Authorized Representative	By _____ Vice President and Director Trade & Pharmacy Affairs - U.S.
Title: President	
Date: July 19, 1999	Date: _____

ATTACHMENTS

Addendum I: Contract Policies and Procedures

EXHIBIT C Impact of Prior Authorization Augmentin Analysis					
Historical Share and Dollar Impact Analysis of a PA Placed on Augmentin at Regional MCO in Nevada					
Unit and DACON WeightedRx Average WAC	$ 80.00				
	Augmentin TRx's	Augmentin Plan Market Share	Percent Change in Market Share	Gross Revenue	Total Loss in Revenue with Flat Class Growth
3Q98	3900	46%		$ 312,00	
4Q98	4053	49%	6.5%	$ 324,240	
1Q99	3599	23%	-50.0%	$ 287,920	$ 36,320
2Q99	645	18%	-60.9%	$ 51,600	$ 272,640
Total Loss in Gross Revenue to Plan					$ 308,960
Percent Loss in Plan Market Share					-60.9%

Assumptions
TRx Quarterly data extrapolated from semester (6 month), quarterly, and monthly "Eagle" data streams. Eagle reports are formatted from plan level NDC retail audits.
Percent Loss in Plan Market Share = variance between 3Q98 and 2Q99 plan market shares
Gross Revenue calculated by multiplying TRx's by average price per indication treated.

EXHIBIT D
Impact of Prior Authorization
Paxil Analysis

Historical Share and Dollar Impact Analysis of a PA Placed on Paxil at National MCO

Unit and DACON WeightedRx Average WAC	$ 66.89				
	PAXIL TRx's	Paxil Plan Market Share	Percent Change in Market Share	Gross Revenue	Total Loss in Revenue with Flat Class Growth
1Q97	40452	21%		2,705,834	
2Q97	32883	17%	-20.7%	2,199,544	$ 506,290
3Q97	24354	15%	-29.9%	1,629,039	$ 1,076,795
4Q97	20805	14%	-32.3%	1,391,646	$ 1,314,188
1Q98	23811	14%	-35.4%	1,592,718	$ 1,113,116
2Q98	23979	14%	-35.2%	1,603,955	$ 1,101,879
3Q98	25668	13%	-36.8%	1,716,933	$ 988,902
4Q98	26070	12%	-41.8%	1,743,822	$ 962,012
Total Loss in Gross Revenue to Plan					$ 7,063,183
Percent Loss in Plan Market Share					-41.8%

Assumptions
TRx Quarterly data extrapolated from semester (6 month), quarterly, and monthly "Eagle" data streams. Eagle reports are formatted from plan level NDC retail audits.
Gross Revenue calculated by multiplying TRx's by Unit and DACON weighted price per month

EXHIBIT E Impact of Prior Authorization Ralafen Analysis					
Historical Share and Dollar Impact Analysis of a PA Placed on Relafen at Large West Coast based MCO					
Unit and DACON WeightedRx Average WAC	$ 63.36				
	Ralefen TRx's	Ralefen Plan Market Share	Percent Change in Market Share	Gross Revenue	Total Loss in Revenue with Flat Class Growth
4Q97	12993	12.8%		$ 823,236	
1Q98	12361	9.4%	-26.6%	$ 783,193	$ 40,044
2Q98	7856	6.6%	-48.%4	$ 497,756	$ 325,480
3Q98	6612	6.5%	-49.2%	$ 418,936	$ 404,300
4Q98	6372	6.3%	-50.8%	$ 403,730	$ 419,507
1Q99	6036	5.2%	-59.4%	$ 382,441	$ 440,796
2Q99	6036	4.9%	-61.7%	$ 382,441	$ 440,796
3Q99	6189	4.6%	-64.1%	$ 392,135	$ 431,101
4Q99	5664	4.2%	-67.2%	$ 358,871	$ 464,365
Total Loss in Gross Revenue to Plan					$ 2,966,388
Percent Loss in Plan Market Share					-67.2%

Assumptions
TRx Quarterly data extrapolated from semester (6 month), quarterly, and monthly "Eagle" data streams. Eagle reports are formatted from plan level NDC retail audits.
Gross Revenue calculated by multiplying TRx's by Unit and DACON weighted price per month

EXHIBIT F
Impact of Prior Authorization
Avandia Analysis

Historical Share and Dollar Impact Analysis of a PA Placed on Avandia at MCO Plan

Unit and DACON WeightedRx Average WAC	$ 87.49					
	Avandia TRx's	Avandia Plan Market Share	Percent Change in Market Share	Gross Revenue	Estimated Gross Sales without PA	Total Loss in Revenue with PA Disadvantage Avandia
Jan-00	325	61%		$ 28,434		
Feb-00	357	55%		$ 31,234		
Mar-00	452	36%	-34.5%	$ 39,545	$ 60,417	$ (20,871)
Apr-00	467	30%	-46.0%	$ 40,858	$ 75,663	$ (34,805)
Total Loss in Gross Revenue to Plan						$ (55,676)
Percent Loss in Plan Market Share						46.0%

Assumptions
Customer has a 70/30 Actos vs Avandia market share split with the PA disadvantaging Avandia
Avandia market share is restated to reflect a 2 product market.
Gross Revenue with PA calculated by multiplying TRx's by Unit and DACON weighted price per month.
Estimated Gross Sales without a PA is calculated by dividing TRx's by Avandia Market Share and multiplying that sum by a 55% market share and DACON weighted price per month.
Percent Loss in Plan market share calculated as a variance between Feb 2000 market share of 55% and April 2000 market share of 30%.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff,	)	Civil Action No. 00-157-B
v.	)	
KEVIN CONCANNON, in his official Capacity as Commissioner of the Department of Human Services For the State of Maine	)	
ANDREW KETTERER, in his official capacity asAttorney General for the State of Maine	)	
Defendants.	)	

DEFENDANTS' ANSWER

The defendants, Kevin Concannon, Commissioner of the Department of Human Services for the State of Maine, and Andrew Ketterer, the Attorney General for the State of Maine, each named in their official capacities, by and through their counsel, the Attorney General for the State of Maine, answer Plaintiff's complaint as follows:

1. The allegations set forth in paragraph 1 of the complaint are legal in nature and do not require a response.

2. The Act speaks for itself. The allegations set forth in paragraph 2 of the complaint are legal in nature and do not require a response, but to the extend they require a response they are denied.

3. The Act speaks for itself. The allegations set forth in paragraph 3 of the complaint are legal in nature and do not require a response, but to the extend they require a response they are denied.

4. Defendants deny the allegations set forth in paragraph 4 of the complaint.

5. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 5 of the complaint.

6. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 6 of the complaint.

7. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 7 of the complaint.

8. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 8 of the complaint.

9. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 9 of the complaint.

10. Defendants admit the allegations set forth in paragraph 10 of the complaint.

11. Defendants admit the allegations set forth in paragraph 11 of the complaint.

12. Defendants admit the allegations set forth in paragraph 12 of the complaint.

13. Defendants admit the allegations set forth in paragraph 13 of the complaint.

14. The allegations set forth in paragraph 14 of the complaint are legal in nature and do not require a response.

15. The allegations set forth in paragraph 15 of the complaint are legal in nature and do not require a response.

16. The allegations set forth in paragraph 16 of the complaint are legal in nature and do not require a response.

17. Defendants deny the allegations set forth in paragraph 17 of the complaint, except defendants admit that the Act enacts a new Chapter 603, entitled "Prescription Drug Access," in Maine Rev. Stat. Ann. Title 22.

18. The Act speaks for itself. The allegations set forth in paragraph 18 of the complaint are legal in nature and do not require a response.

19. The Act speaks for itself. The allegations set forth in paragraph 19 of the complaint are legal in nature and do not require a response.

20. Defendants admit that Maine residents who do not have prescription drug coverage under other public or private program will qualify for the Maine Rx Program to be administered by the Department, and that the number of such residents is presently estimated at 325,000. Otherwise, the allegations set forth in paragraph 20 of the complaint are denied.

21. The Act speaks for itself. The allegations set forth in paragraph 21 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

22. The Act speaks for itself. The allegations set forth in paragraph 22 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

23. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 23 of the complaint.

24. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 24 of the complaint.

25. The Act speaks for itself. The allegations set forth in paragraph 25 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

26. The Act speaks for itself. The allegations set forth in paragraph 26 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

27. The Act speaks for itself. The allegations set forth in paragraph 27 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

28. Defendants deny the allegations set forth in paragraph 28 of the complaint, except Defendants admit that on August 2, 2000 the Commissioner sent to pharmaceutical manufacturers a "Rebate Agreement" which defines the rebate amount being sought as equal to the Medicaid rebate, and that the Commissioner requested that executed Rebate Agreements be returned to the Department by November 1, 2000.

29. The Act speaks for itself. The allegations set forth in paragraph 29 for the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

30. The Act speaks for itself. The allegations set forth in paragraph 30 of the complaint are legal in nature and do not require a response, but to the extent they do require a response they are denied.

31. Defendants deny the allegations set forth in paragraph 31 of the complaint.

32. The Act speaks for itself. The allegations set forth in paragraph 32 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

33. The Act speaks for itself. The allegations set forth in paragraph 33 of the complaint are legal in nature and do not require a response.

34. The Act speaks for itself. The allegations set forth in paragraph 34 of the complaint are legal in nature and do not require a response, but to the extend they require a response, they are denied.

35. The Act speaks for itself. The allegations set forth in paragraph 35 of the complaint are legal in nature and do not require a response.

36. Defendants admit the allegations set forth in paragraph 36 of the complaint.

37. The relevant Acts speak for themselves. The allegations set forth in paragraph 37 of the complaint are legal in nature and do not require a response.

38. The Act speaks for itself. The allegations set forth in paragraph 38 of the complaint are legal in nature and do not require a response.

39. The Act speaks for itself. The allegations set forth in paragraph 39 of the complaint are legal in nature and do not require a response.

40. The Act speaks for itself. The allegations set forth in paragraph 40 of the complaint are legal in nature and do not require a response, but to the extent they require a response, they are denied.

41. The Act speaks for itself. The allegations set forth in paragraph 41 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

42. The Act speaks for itself. The allegations set forth in paragraph 42 of the complaint are legal in nature and do not require a response.

43. The Act speaks for itself. The allegations set forth in paragraph 43 of the complaint are legal in nature and do not require a response.

44. The Act speaks for itself. The allegations set forth in paragraph 44 of the complaint are legal in nature and do not require a response.

45. The Acts speak for themselves. The allegations set forth in paragraph 45 of the complaint are legal in nature and do not require a response.

46. The Act speaks for itself. The allegations set forth in paragraph 46 of the complaint are legal in nature and do not require a response.

47. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 47 of the complaint are legal in nature and do not require a response.

48. The Omnibus Budget Reconciliation Act of 1990 speaks for itself. The allegations set forth in paragraph 48 of the complaint are legal in nature and do not require a response.

49. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 49 of the complaint are legal in nature anti do not require a response.

50. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 50 of the complaint are legal in nature and do not require a response.

51. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 51 of the complaint are legal in nature and do not require a response.

52. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 52 of the complaint are legal in nature and do not require a response.

53. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 53 of the complaint are legal in nature and do not require a response.

54. Paragraph 54 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

55. The allegations set forth in paragraph 55 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

56. The allegations set forth in paragraph 56 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

57. Defendants deny the allegations set forth in paragraph 57 of the complaint.

58. Defendants deny the allegations set forth in paragraph 58 of the complaint.

59. Paragraph 59 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

60. The allegations set forth in paragraph 60 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

61. Defendants deny the allegations set forth in paragraph 61 of the complaint.

62. Defendants deny the allegations set forth in paragraph 62 of the complaint.

63. Defendants deny the allegations set forth in paragraph 63 of the complaint.

64. Paragraph 64 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

65. The allegations set forth in paragraph 65 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

66. Defendants deny the allegations set forth in paragraph 66 of the complaint.

67. Defendants deny the allegations set forth in paragraph 67 of the complaint.

68. Defendants deny the allegations set forth in paragraph 68 of the complaint.

69. Paragraph 69 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

70. The allegations set forth in paragraph 70 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

71. Defendants deny the allegations set forth in paragraph 71 of the complaint.

72. Defendants deny the allegations set forth in paragraph 72 of the complaint.

73. Defendants deny the allegations set forth in paragraph 73 of the complaint.

74. Paragraph 74 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

75. The allegations set forth in paragraph 75 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

76. Defendants deny the allegations set forth in paragraph 76 of the complaint.

77. Defendants deny the allegations set forth in paragraph 77 of the complaint.

78. Defendants deny the allegations set forth in paragraph 78 of the complaint.

79. Paragraph 79 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

80. Defendants admit the allegations set forth in paragraph 80 of the complaint.

81. Defendants deny the allegations set forth in paragraph 81 of the complaint.

82. Defendants deny the allegations set forth in paragraph 82 of the complaint.

DEFENSES

1. Plaintiff's claims are barred by the Market Participation exception to the Commerce Clause.

2. Plaintiff's claims are not ripe.

3. Plaintiff's claims are not justiciable under Article III of the United States Constitution.

4. Plaintiff's complaint fails to state a claim or claims upon which relief may be granted.

5. Plaintiff lacks standing to bring the claims alleged in the complaint.

6. The defendants are sued in their official capacities. To the extent Plaintiff seeks damages, such an action is barred by the Eleventh Amendment and the doctrine of sovereign immunity.

Dated: September 11, 2000
Augusta, Maine

ANDREW KETTERER
Attorney General

/s/

by: Andrew S. Hagler
Assistant Attorney General
6 State House Station
Augusta, Maine 04333
(207) 626-3800
Attorney for the Defendants

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff

v.

Civil Action No.
00-157-B

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services For the State of Maine
and
ANDREW KETTERER, in his official capacity as Attorney General For the State of Maine

Defendants.

AFFIDAVIT OF TIMOTHY S. CLIFFORD, M.D.

TIMOTHY S. CLIFFORD, M.D., being duly sworn, deposes and says that the following is true and correct and based upon personal knowledge:

1. My name is Dr. Timothy S. Clifford. Since April, 1996, I have been the Medical Director for the Maine Bureau of Medical Services, which administers the state's Medicaid Program. I am also a practicing Family Physician in Bucksport, Maine with 15 years experience.

2. In my role as Medicaid Medical Director I decide, in conjunction with the Maine Medicaid Drug Utilization Review ("DUR") Committee, which drugs are to be prior authorized and under which conditions particular requests for prior authorization will be granted. I personally review all

drug prior authorization requests which require the clinical determination of a physician.

3. I have read the declaration submitted by Dr. Scott Howell on behalf of the plaintiff in this action.

4. I disagree with Dr. Howell's suggestion that, when a particular drug is subject to a prior authorization requirement, physicians and pharmacists must obtain permission each time that drug is prescribed or dispensed to a particular patient.

5. The Maine Medicaid program does not require a physician to seek permission each time they wish to prescribe a drug subject to a prior authorized requirement. For the vast majority of drugs with prior authorization requirements, an authorization obtained from my office will permit a pharmacy to dispense that drug to that patient for as many times as the physician finds medically necessary, within a 6-12 month period. A smaller percentage of other drugs with prior authorization requirements may be prescribed, as deemed necessary by the physician, within a 3 month period. Only if specifically requested by the physician will the authorization obtained from my office be limited to less than 3 months.

6. I also disagree with Dr. Howell's suggestion that the purpose of imposing a prior authorization requirement on the use of a particular drug is to limit the use of that drug.

7. The primary purpose of a prior authorization requirement is to ensure that a drug is not being used inappropriately.

8. I also disagree with Dr. Howell's suggestion that the Department will not address safety and efficacy concerns in administering the prior authorization mechanism of the Maine Rx Program. I further disagree with the suggestion that the Department will not consider the availability of alternative drugs in making the decision of whether to subject a particular drug to a prior authorization requirement. Finally, I disagree with Dr. Howell's conclusion that the Department's

implementation of the prior authorization mechanism of the Maine Rx Program will limit the access of Medicaid recipients to medically necessary drugs.

[9]. The Maine Medicaid Program always has considered, and the Maine Rx Program always will consider, the safety, efficacy and availability of other drugs in its implementation of the prior authorization process. The Department certainly will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process, regardless of whether the manufacturers participates in Maine Rx Program by entering into rebate agreements. The Department has drafted proposed administrative rules governing the use of the prior authorization provision of the Maine Rx Program. These rules require that the determination of whether a particular drug should be subjected to a prior authorization requirement be made by physicians and pharmacists sitting on the Maine Medicaid Drug Utilization Review Committee. These rules also require that the determination of whether a particular drug should be subjected to a prior authorization requirement will be based firmly upon considerations of medical necessity, and in compliance with the State's responsibilities as the administrator of the Maine Medicaid Program.

[10]. I also disagree with Dr. Howell's statement that the Maine Rx Program prior authorization provision will be implemented so as to impose significant and gratuitous burdens on Medicaid healthcare providers and patients, and that patients will, as a result, be denied access to the safest and most efficacious drugs.

[11]. Physicians in Maine are already well acquainted with the extensive prior authorization programs of the four HMO/Insurance programs which collectively cover nearly half the state's residents. As explained above, in implementing the prior autnorization provision of the Maine Rx Program, the Department will ensure that physicians will

always be able to prescribe the safest and most efficacious drugs for their Medicaid patients.

[12]. I also disagree with Dr. Howell's statement that prior authorization requirements cause doctors to switch from first-choice drugs to potentially less safe and effective second-choice drugs. The fundamental fallacy of this statement is the notion that the so-called "first choice" drug is always the safest and the most effective drug in all situations. A number of studies and Drug Utilization Review Programs have disproved this wildly inaccurate claim. For example, our Maine's Drug Utilization Review Program sends out nearly 1,000 letters a month to physicians warning them of potentially dangerous drug/drug and drug/disease interactions on recent prescriptions they have written and of which they are often unaware. Furthermore, our pharmacy point of purchase claims processing system alerts pharmacists to thousands of other dangerous drug/drug interactions, thereby preventing the filling of dangerous prescriptions. Thus, whether or not a prior authorization requirement applies to a specific drug, the "first choice" is often not the best choice. In fact, a well designed prior authorization program can improve safety and insure that the "first choice" drug is used appropriately.

[13.]. I also disagree with the claims Dr. Howell makes on behalf of his company's drug, *Augmentin*. Specifically, I disagree with Dr. Howell's attempt to suggest that the Centers for Disease Control unequivocally recommends *Augmentin*, for the treatment of *otitis media*, or ear infections.

[14]. In truth, the Centers for Disease Control recommended the broad spectrum antibiotic, *Augmentin*, as a second line medication in the treatment of ear infections only after an attempt to treat the condition with *Amoxicillin*, a far less expensive, and more "narrow band" antibiotic, have failed.

[15]. I also disagree with Dr. Howell's suggestion that implementation of the prior authorization provision of the Maine Rx Program will not involve a thoughtful process designed to achieve safety, efficacy, and cost-effectiveness in the dispensing of prescription drugs to Medicaid recipients.

[16]. The Department has in place adequate safeguards to ensure the best clinical treatment and safety of Medicaid patients. The Department currently employs two (2) full time pharmacists, two (2) part-time pharmacists and it contracts for the additional specialized services of four (4) other pharmacists. An active Drug Utilization Review Committee exists and that committee, and the Department, actively solicit and receive the advice from a variety of Health Maintenance Organizations, state and federal government agencies and health care professionals. In contrast to prior authorization programs established by private insurers, our program must comply with a variety of State and Federal laws and regulations which are in place to ensure that Medicaid recipients receive the drugs which are for them medically necessary. Accordingly, implementation of the prior authorization provision of the Maine Rx Program will involve the same thoughtful process we have always employed to ensure safety, efficacy, cost-effectiveness, so as to benefit all Medicaid recipients.

Dated: 9/7/00

/s/
TIMOTHY S. CLIFFORD, M.D.

STATE OF MAINE
KENNEBEC, ss

Before me this day personally appeared Timothy S. Clifford, M.D., who being duly sworn, deposes and says that the statements in the above affidavit of same, are true.

/s/

Name of Notary Public:
Notary Public, State of Maine
My Commission Expires:

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA	*	
Plaintiff,	*	
v.	*	Civil Action
	*	No. 00-157-B
KEVIN CONCANNON, Commissioner Of Maine Department of Human Services	*	
ANDREW KETTERER, Attorney General State of Maine	*	
Defendants.	*	

* * * * * * *

AFFIDAVIT OF H. BURTT RICHARDSON, JR, M.D.

I, Burtt Richardson, being duly sworn, state as follows:

1. This affidavit is based upon my personal knowledge, information and belief.

2. My name is H. Burtt Richardson, Jr. I am a pediatrician and a Maine Medicaid provider. A current and accurate copy of my resume is attached as Exhibit A to this Affidavit.

3. I have been a Maine Medicaid provider for 22 years.

4. My practice can be broken down into the following categories: approximately 18% is Medicaid (including the Cub Care program); 30% is HMO (HealthSource, Blue Cross Blue Shield, etc.); 30% is insured with non-HMO's; 12% insured with high deductible (uninsured for primary care); and 10% are uninsured.

5. My practice ranks in the 72nd percentile of Maine pediatricians who treat Maine Medicaid children, in terms of the number of Medicaid-insured children seen per year.

6. I believe that most HMO's punish particular drug manufacturers who fail to negotiate competitive practices by disapproving certain drugs in their formularies.

7. The Maine Medicaid Program does not currently use the prior authorization of drugs to punish particular drug manufacturers for any reason.

8. I prescribe Augmentin as a second line drug after another drug, usually high dose amoxicillin, has failed to adequately treat an ear infection. Augmentin is 3 to 6 times as expensive as amoxicillin, and amoxicillin is effective in treating ear infections 80-85% of the time.

9. I know that some of my non-Medicaid patients cannot afford their medication. They have told me they were not able to purchase a prescription and they have asked for a less expensive alternative or a sample.

10. I have personally observed the parents of some of my non-Medicaid patients get my bill for service and show my bill to their children saying "see how much you cost us." I have observed that this scenario makes children feel guilty about being sick.

11. I welcome the Maine Rx Program law because it is attempting to reduce the price of drugs to some of my patients who do not have drug insurance benefits and who might otherwise not be able to afford medications.

12. I approve of the Maine Rx Program prior authorization procedure so long as the decision to put a prior authorization on particular drugs is clinically appropriate, feasible for a medical office, and accompanied by the assurance that all Maine Medicaid recipients have access to medically necessary drugs.

Dated: 9-7-00

/s/
H. Burtt Richardson, Jr., M.D.

Personally appeared before me this 7th day of September, 2000, the above-named H. Burtt Richardson, Jr., and made oath that the foregoing statements are true based upon his personal knowledge, information and belief.

Dated: 9/7/00

/s/
Notary Public/Attorney at Law

DONNA A. HEAVENER
Notary Public • State of Maine
My Commission Expires 2/13/07

[Exhibit A]

CURRICULUM VITAE

RICHARDSON, HENRY BURTT, JR., M.D., F.A.A.P.

Pediatrician
Winthrop Family Pediatrics Center
R.F.D. 3 Box 9
Winthrop, Maine 04364
Phone 207-377-2114

BORN: Passaic, New Jersey – November 20, 1934

CITIZENSHIP: U.S.A.

EDUCATION: Haverford College,
Haverford, Pennsylvania
Temple University School of Medicine,
Philadelphia, Pennsylvania

DEGREES: A.B., Haverford College—June 1956
M.D., Temple University—June 1960

POST GRADUATE TRAINING:

July 1960—June 1961 Rotating Internship—State University of New York,
Upstate Medical Center Hospitals,
Syracuse, New York

July 1961—June 1963 Residency in Pediatrics,
St. Christopher's Hospital for Children,
Philadelphia, Pennsylvania

September 1967—August 1968 USPHS Traineeship in Neurological and SensoryDisease (Mental Retardation),
Children's Diagnostic and Development Center,
Georgetown University Hospital,
Washington, D.C.

MEDICAL LICENSURE:

Pennsylvania—August 1961
District of Columbia—April 1968
Virginia—June 1971
Maine—July 1975

BOARD CERTIFICATION:

Diplomate American Board of Pediatrics—May 1965
Recertified June 1983

MILITARY SERVICE:

Captain, United States Air Force (Medical Corps);
Base Pediatrician, Davis Monthan AFB,
Tucson, Arizona,
July 1963—June 1965

APPOINTMENTS:

Chief of Medical Unit (Peru), The People-to-People Health Foundation, Incorporated (Project HOPE). Trujillo, Peru, August 1965—July 1967

Visiting Professor of Pediatrics, National University of Trujillo. Peru, August 1965—July 1967

Attending Pediatrician, Children's Hospital National Medical Center, September 1968—December 1975

Assistant Professor of Pediatrics, George Washington University School of Medicine, September 1968—July 1971

Associate Director, Program for Learning Studies, Children's Hospital National Medical Center, September 1970—September 1974

Associate Professor of Child Health and Development, George Washington University School of Medicine, July 1971—July 1977

Visiting Professor and Consultant in Ambulatory Pediatrics, University of Arizona College of Medicine, March & April, 1974

Associate Director, Pediatric Training Program, Children's Hospital National Medical Center, October 1974—July 1977

Senior Attending Pediatrician and Vice Chairman, Department of General Medicine, Children's Hospital National Medical Center, January 1976—July 1977

Adjunct Associate Professor of Child Health and Development, George Washington University School of Medicine, July 1977—June 1980

Consultant Pediatrician, The People-to-People Health Foundation, Incorporated (Project HOPE), Trujillo, Peru, July 1977—January 1978

Attending Pediatrician, Kennebec Valley Medical Center, Augusta, Maine, January 1978—to present

Pediatrician, Winthrop Area Medical Center, Winthrop, Maine, January 1978—July 1984

Pediatrician, Winthrop Family Pediatrics Center, Winthrop, Maine, July 1984—to present

SOCIETY MEMBERSHIP

Pima County Pediatric Society	1963—1965
Sociedad Pediatricia de Trujillo	1956—1968

American Academy of Pediatrics	1968—to present
Medical Society of the District of Columbia	1969—1978
Society for Neuroscience	1970—1978
Maine Medical Association	1978—1980; 1986—to present

INVESTIGATIVE EXPERIENCE:

Two studies were carried out between 1961 and 1963, one concerning the laboratory diagnosis and clinical management of salicylate intoxication with gradation of severity and the other concerning the two-year residency experience with in-patients classified according to disease category. Between 1963 and 1965, clinical investigations were carried out relating to (1) epidemic infection with coxsackie A-16, (2) coccidioidomycosis, (3) the treatment of acute otitis media, and (4) the diagnosis and therapy of acute promazine intoxication.

Between 1965 and 1967, four studies were carried out in Peru regarding health conditions in a shanty-town community. These involved (1) the prevalence of diarrhea in infants and young children, (2) the nutritional state of infants and children between 6 months and 6 years of age, (3) the dietary habits of children under 15 years of age, and (4) the socio-economic and sanitary conditions of 100 families. An additional report was prepared concerning the introduction of family medicine concepts into the curriculum of the clinical years in a Latin American medical school.

Investigative activities from 1967 to 1977 involved (1) the development of diagnostic approaches to young children with learning or vision problems; (2) the implementation of interdisciplinary services for children with learning problems in health and public school settings; (3) the development of training programs subject to systematic evaluation for professionals and non-professionals working in child health and development areas; (4) planning and evaluation of large

scale health and child development services in school-aged children; and (5) the planning and evaluation of house officer curriculum in general pediatrics and child development.

Since 1978, focus has been on the introduction of health promotion education into school health programs and into the private practice of pediatrics and the design, implementation and evaluation of a developmental pediatrics curriculum for residents as chairperson of a national task force. Since 1982, investigations have included the effectiveness of early educational intervention for handicapped children and practical approaches to the prevention of developmental disabilities.

PUBLICATIONS (Articles):

1. Richardson, H.B., Jr., and Leibovitz, A.: Hand, foot and mouth disease in children: an epidemic associated with Coxsackie virus A-16, Journal of Pediatrics 67: 6-12, 1968.
2. Richardson, H.B., Jr., Anderson, J.A., and McKay, B.M., Acute pulmonary coccidioidemycosis in children. Journal of Pediatrics 70: 376-382, 1967.
3. Medina, T., Javier, and Richardson, H.B., Jr.: Estudio de diarrhea en una poblacion de barrriada; prevalencia en infantes y ninos menores y uso de un metodo de tratamiento standard. (Study of diarrhea in a shanty-town population; prevalence in infants and small children and use of a standard treatment method.) Transacciones del V Congreso Peruano de Pediatria (April, 1966).
4. Bartalos, M., and Richardson, H.B., Jr., Aneusomy by recombination: a possible example involving E-18 chromosome. Acta Genetica Medica et Gemellologiae (Rome) 18: 117-124, 1969.
5. Christopolos, Florence, Costenbader, Frank D., Goldberg, Herman K., Mills, Jack, and Richardson H. Burtt, Jr., Symposium on Dyslexia. Bulletin of the Washington Hospital Center. Vol. 1, 1: 5-25, 1970.
6. Richardson, H. Burtt, Jr., and Ozer, Mark N.: Diagnostic evaluation of children with learning problems: role of the pediatrician. Clinical Proceedings, Children's Hospital National Medical Center, Vol. 26: 119-125, 1970.
7. Ozer, Mark N., Richardson, H. Burtt, Jr., Tannhauser, Miriam, and Smith, Cora: Diagnostic evaluation of children with learning problems: An Interdisciplinary Clinic Model. Clinical Proceedings, Children's Hospital National Medical Center, Vol. 26: 166-177, 1970.
8. Ozer, Mark N., and Richardson, H. Burtt, Jr.: The diagnostic evaluation of children with learning problems: a communication process. Childhood Education 244-247, 1972.
9. Ozer, Mark N., and Richardson, H. Burtt, Jr.: The diagnostic evaluation of children with learning problems: a "process" approach. Journal of Learning Disabilities, 88-92, 1974.
10. Richardson, H. Burtt, Jr., Guralnick, Michael J., and Tupper, Deborah B.: Training pediatricians for effective involvement with handicapped preschool children and their families. Mental Retardation, Vol. 16, 1: 3-7, 1978.
11. Richardson, H. Burtt, Jr., and Guralnick, Michael J.: Pediatric residents and young handicapped children: curriculum evaluation. Journal of Medical Education, Vol. 53: 487-492, 1978.
12. Guralnick, Michael J., Richardson, H. Burtt Jr., and Heiser, Karen E.: A curriculum in handicapping conditions for pediatric residents. Exceptional Children, Vol. 48, 383-346, 1982.
13. Bennett, Forrest C., Guralnick, Michael J., Richardson, H. Burtt, Jr., and Heiser, Karen E.: Teaching developmental

pediatrics to residents: effectiveness of a structured curriculum. Pediatrics 74: 514-522, 1984.

14. Guralnick, Michael J., Bennett, Forrest C., Heiser, Karen E., and Richardson, H. Burtt, Jr., Training future primary care pediatricians to serve handicapped children and their families. Topics in Early Childhood Special Education, Vol 6: 1-11, 1987.

15. Guralnick, Michael J., Bennett, Forrest C., Heiser, Karen E., Richardson, H. Burtt, Jr., and Shibley, R.E., Jr.: Training residents in developmental pediatrics: results from a national replication. Journal of Development and Behavioral Pediatrics, Vol. 8: 260-265, 1987.

16. Guralnick, Michael J., Heiser, Karen E., Eaton, A.P., Bennett, Forrest C., and Richardson, H. Burtt, Jr., and Groom, J.M.: Pediatricians' perceptions of the effectiveness of early intervention for at-risk and handicapped children. Journal of Developmental and Behavioral Pediatrics, Vol. 9: 12-18, 1988.

PUBLICATIONS (BOOKS):

1. *Pediatric Education and The Needs of Exceptional Children*. Guralnick, Michael J., and Richardson, H. Burtt, Jr., (Editors). Baltimore: University Park Press, 1980.

PUBLICATIONS (CHAPTERS):

1. Richardson, H. Burtt, Jr.: Relationship of research to health and educational services. Chapter in *Early Experience and Visual Information Processing In Perceptual and Reading Disorders*. (F.A. Young and D.B. Lindsley, Eds.) Washington, National Academy of Sciences, 1970, pp. 467-473.

2. Ozer, Mark N., and Richardson, H. Burtt, Jr.: "Diagnosis" in relation to children with learning problems: the use of models. Chapter in *Cybernetics Technique in*

Brain Research and the Educational Process. Washington, D.C., American Society for Cybernetics, 1973, pp. 90-102.

3. Guralnick, Michael J., Richardson, H. Burtt, Jr., and Kutner, Douglas R.: Pediatric education and the development of exceptional children. Chapter in Guralnick, Michael J., and Richardson, H. Burtt, Jr., *Pediatric Education and The Needs of Exceptional Children*. Baltimore, University Park Press. 1980 pp. 2-19.

4. Richardson, H. Burtt, Jr., and Guralnick, Michael J.: An evaluation strategy for pediatric rotations on the needs of exceptional children. Chapter in Guralnick, Michael J., and Richardson, H. Burtt, Jr., *Pediatric Education and the Needs of Exceptional Children*. Baltimore, University Park Press, 1980, pp. 129-135.

5. Richardson, H. Burtt, Jr., Guralnick, Michael J., Taft, Lawrence T., and Levine, Melvin D.: A comprehensive curriculum in child development and handicapping conditions. Prospects for design, implementation and evaluation. Chapter in Guralnick, Michael J., and Richardson, H. Burtt, Jr., *Pediatric Education and the Needs of Exceptional Children*. Baltimore, University Park Press, 1980. pp. 185-202.

6. Richardson, H. Brutt, Jr., and Guralnick, Michael J.: Physician education in developmental-behavioral pediatrics. Chapter in Levine, Melvin D., et al., *Developmental-Behavioral Pediatrics*. Philadelphia, W.B. Saunders and Co., 1983, pp. 1210-1219.

7. Richardson, H. Burtt, Jr.: Pediatrics and developmental disabilities: the state of the art in pediatrics. Chapter in *Alliances in Health and Education for Disabled Children and Youth: Directions for the 80's*. Washington, D.C., American Society of Allied Health Professionals 1983.

8. Guralnick, Michael J., Heiser, Karen E., Bennett, Forrest C., and Richardson, H. Burtt, Jr.: A systems approach to training pediatricians in the field of developmental disabilities. In M.D. Powers (Ed.), *Severe Developmental Disabilities: Expanded Systems of Interaction*. Baltimore, Brookes. 1987, pp. 255-271.

9. Bennett, Forrest C., Guralnick, Michael J., Heiser, Karen E., and Richardson, H. Burtt, Jr.: Training in developmental pediatrics. In M.L. Wolraich and D.K. Routh (Eds.), *Advances in Developmental and Behavioral Pediatrics*. (Vol. 8) Greenwich, CT: JAI Press. 1987, pp. 99-124.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff

v. Civil Action No. 00-157-B

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services For the State of Maine
and
ANDREW KETTERER, in his official capacity as Attorney General For the State of Maine

Defendants.

AFFIDAVIT OF KEVIN CONCANNON

KEVIN CONCANNON, being duly sworn, deposes and says that the following is true and correct and based upon personal knowledge:

1) My name is Kevin Concannon. I am the Commissioner of the State of Maine Department of Human Services (the "Department"). I submit this affidavit in opposition to the plaintiff's motion for a preliminary injunction in the above-captioned action.

2) Title 22 M.R.S.A. §2681, et seq., assigns to the Department the responsibility of administering the newly enacted Maine Rx Program, a program designed to make prescription drugs more affordable for residents of Maine who do not otherwise have prescription drug benefits through

private insurance or public medical assistance programs. The program will commence on January 1, 2001.

3) While the precise number of Maine residents who will be eligible to enroll in the Maine Rx Program is not known at this time, the current Department estimate is that 325,000 persons may be eligible to enroll in the program.

4) Title 22 M.R.S.A. §2681(4) instructs the Commissioner of the Department to negotiate with drug manufacturers and labelers for drug rebates to be paid into the Maine Rx Program. In furtherance of that mandate, on August 2, 2000 I sent the Department's proposed Maine Rx Program Rebate Agreement ("Rebate Agreement") to manufacturers of prescription drugs. A copy of the Rebate Agreement is attached to this affidavit as exhibit A.

5) As is set forth in Section II of the Rebate Agreement, the first Maine Rx Program rebate payment from participating manufacturers, for drugs dispensed through the program during the first quarter of its operation will be due no earlier than September 30, 2001.

6) As of today, twenty-seven (27) prescription drug manufacturers have elected to participate in the Maine Rx Program by executing Maine Rx Program Rebate Agreements.

7) The Bureau of Medical Services is the branch of the Maine Department of Human Services charged with overseeing and administering the Medicaid Program.

8) 22 M.R.S.A. §2681(7) instructs the Department to impose prior authorization requirements in the Medicaid program, as permitted by law, for the dispensing of prescription drugs provided by manufacturers and labelers which do not enter into Maine Rx Rebate Agreements.

9) The Department will not impose a prior authorization requirement in the Medicaid program, pursuant to 22 M.R.S.A. §2681(7), where the imposition of such a

requirement would conflict with the requirements of the Medicaid program. Prior authorization requirements will not be implemented so as to prevent Medicaid recipients from obtaining medically necessary prescription drugs.

10) The Department is in the process of drafting administrative rules for the Maine Rx Program and drafting proposed amendments to the Medicaid rules. These new rules, and rule amendments, will be proposed according to the procedures set forth in the State of Maine Administrative Procedures Act. A copy of the current draft of the portion of the rules involving implementation of Maine Rx Program "prior authorization" provision are attached to this affidavit as exhibit B.

11) Pursuant to these proposed rules, Maine's Medicaid Drug Utilization Review Committee ("DUR Committee"), an advisory board comprised of physicians and pharmacists who are licensed to prescribe or dispense medications in Maine, will make the final determination of the clinical appropriateness of any recommendation that a prior authorization requirement be imposed with respect to a particular prescription drug manufactured by a manufacturer which has not entered into a Maine Rx Rebate Agreement. In making its determination of whether or not a prior authorization requirement is clinically appropriate, the DUR Committee shall be guided by the law of Medicaid, and particularly the principle that Medicaid recipients shall be assured access to all medically necessary prescription drugs.

12) The State of Maine purchases large quantities of prescription drugs on behalf of Medicaid recipients. A chart prepared by the Department which summarizes the State's drug purchasing activity in the Medicaid program over that last three fiscal years is attached to this affidavit as exhibit C.

Dated: September 8, 2000

/s/
KEVIN CONCANNON, COMMISSIONER

STATE OF MAINE
KENNEBEC, ss

Before me this day personally appeared Kevin Concannon, who being duly sworn, deposes and says that the statements in the above affidavit of same, are true.

/s/ Marie Lahaye
Name of Notary Public
Notary Public, State of Maine
My Commission Expires: 1-5-2005

[Exhibit A]

MAINE RX PROGRAM REBATE AGREEMENT

BETWEEN

THE COMMISSIONER OF THE DEPARTMENT OF HUMAN SERVICES OF THE STATEOF MAINE

AND

THE MANUFACTURER IDENTIFIED IN SECTION VIII

OF THIS AGREEMENT

(Hereinafter referred to as the "Manufacturer")

The Commissioner, on behalf of the State of Maine, and the Manufacturer, on its own behalf for the purposes of complying with Public Law 1999, chapter 786, hereby agree to the following:

I. DEFINITIONS

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified herein:

(a) "*AVERAGE WHOLESALE PRICE*" means the Wholesale Price charged on a specific commodity that is assigned by the drug Manufacturer and is listed in a nationally recognized drug-pricing file.

(b) "*CALENDAR QUARTER*" means four times a year. Specifically the first Calendar Quarter will be from January 1, 2001 — March 31, 2001. Each successive three-month period shall be a Calendar Quarter.

(c) "*COMMISSIONER*" means the Commissioner of the Department of Human Services.

(d) "*DEPARTMENT*" means the Department of Human Services.

(e) "*MANUFACTURER*" means the entity holding legal title or possession of the National Drug Code (NDC) for the Prescription Drug.

(f) "*NATIONAL DRUG CODE* (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this Agreement, the complete 11-digit NDC will be used including the labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or -formulation), and package size code to identify a prescription drug.

(g) "*NET SALES*" means Calendar Quarter gross sales revenue less cash discounts allowed and all other price reductions which reduce the actual price paid; and as discussed under the definition of WP.

(h) "*PRESCRIPTION DRUG*" means (1) legend drugs, defined as drugs carrying the statement "Caution: Federal Law Prohibits Dispensing Without A Prescription" and (2) any other drugs which by State law or regulation require the prescription of a licensed practitioner for dispensing. For purposes of this Agreement, all Prescription Drugs must be identified by the Manufacturer's labeler code segment of the National Drug Code (NDC).

(i) "*QUALIFIED RESIDENT*" means a resident of the State who has obtained from the Department a Maine Rx enrollment card.

(j) "*REBATE AMOUNT*" means the Medicaid Rebate amount.

(k) "*REBATE PAYMENT*" means, with respect to the Manufacturer's Prescription Drugs, the Calendar Quarter payment by the Manufacturer to the State of Maine which shall be the sum of the Rebates of each prescription drug (computed for each dosage form and strength of each Prescription Drug) calculated as follows:

(1) The total number of Units paid under the Maine Rx Program for qualified residents during the Calendar Quarter multiplied by the Rebate amount per Unit.

(2) Effective January 1, 2001, a percentage equal to the Medicaid Rebate percentage to the State of Maine in effect for the corresponding time period.

(l) "*UNIT*" means drug Unit in the lowest identifiable amount (i.e. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the Unit for each dosage form and strength of each Prescription Drug in accordance with instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate program under Section 1927 of the Social Security Act.

(m) "*UTILIZATION DATA*" means the information regarding the total number of Units of each dosage form and strength of the Manufacturer's Prescription Drugs paid during the Calendar Quarter under the Program. Drugs dispensed prior to January 1, 2001 are excluded. The Utilization Data includes: (1) 11-digit NDC, including package size code; (2) product name; (3) quantity of Units paid during the Calendar Quarter by 11-digit NDC; (4) total number of prescriptions paid during the Calendar Quarter by 11-digit NDC; and (5) total dollar amount paid during the Calendar Quarter by 11-digit NDC.

(n) "*WHOLESALE PRICE* (WP)" means, with respect to a Prescription Drug of the Manufacturer for a Calendar Quarter the average price paid by Wholesalers in the United States to the Manufacturer, for ultimate distribution to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to Wholesalers where the drug is relabeled under that distributor's national drug code). WP includes cash discounts allowed and all other price reductions, which reduce the actual price paid. It is calculated as a weighted average of prices for a Manufacturer's package sizes for each Prescription Drug by the Manufacturer during that Calendar Quarter. Specifically it is calculated as Net Sales divided by number of Units sold, excluding drugs or any other items given away but not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the Units of each drug sold under the bundled arrangement. The V/P for a Calendar Quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjusted the prices actually realized.

(o) "*WHOLESALER*" means any entity (including a pharmacy or chain of pharmacies) to which the Manufacturer sells the Prescription Drug, but that does not re-label or repackage the Prescription Drug.

II. MANUFACTURER'S RESPONSIBILITIES

The Manufacturer agrees to the following:

(a) To calculate and to make a Rebate Payment each Calendar Quarter to the State of Maine for the Manufacturer's Prescription Drugs paid for by the Department pursuant to the Maine Rx Program during a Calendar Quarter under the Maine Rx Program as follows:

Manufacturer's first rebate payment for the Calendar Quarter January 1, 2001 through March 31, 2001 shall be due September 30, 2001, or 30 days after receipt of utilization data pursuant to Section III (a) of this Agreement, whichever is later.

All subsequent Rebate payments will be made by the Manufacturer to the State of Maine within 30 days of the close of each Calendar Quarter, or within 30 days upon receipt of the Utilization. Data pursuant to Section III (a) of this Agreement, whichever is later. Simultaneously, with each Rebate Payment, the Manufacturer will provide the Department with the Manufacturer's most recent price catalog, unless no price changes were made from the previous Calendar Quarter.

(b) To continue to make a Rebate Payment to the State of Maine on all of its Prescription Drugs as defined in this Agreement so long as this Agreement, or a successor Agreement, is in force and as long as such Prescription Drugs are dispensed under the Manufacturer's NDC. If there are no sales by the Manufacturer during a Calendar Quarter the WP used for the most recent Calendar Quarter in which sales occurred will continue to be used in calculating Rebates.

(c) The Manufacturer will be responsible for Rebates on claims for prescription drugs that were dispensed within one year of the date that the claim was paid by the Department.

(d) The Manufacturer agrees to maintain all books, documents, papers, accounting records, and any other evidence pertaining to this Agreement and make such material available at its offices during normal business hours and shall send copies of such material to the Department upon the request of the Department during the period of this Agreement and for a period of two years after the termination of this Agreement. The

Manufacturer shall allow inspection of pertinent documents by the Department or any authorized representative of the State of Maine, and shall furnish copies thereof, if requested.

III. COMMISSIONER'S RIGHTS AND RESPONSIBILITIES

(a) The Department, on behalf of the Commissioner, shall send the Utilization Data as defined in this Agreement, to the Manufacturer, by certified mail, return receipt requested, within 60 days following the last day of each Calendar Quarter for qualified residents. The Commissioner, through the Department, shall maintain electronic claims records for the most recent four Calendar Quarters that will permit the Manufacturer to verify through an audit process The Utilization Data provided by the Department.

(b) The Department shall conduct audits, as it deems necessary to verify rebate calculation and payment.

IV. DISPUTE RESOLUTION FOR DISCREPANCIES IN REBATE AMOUNTS

Discrepancies in Rebate amounts must be resolved using the following process:

(a) If there is a discrepancy in the Manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the Manufacturer or labeler, the Department, at the Department's expense, may hire a mutually agreed-upon auditor. If a discrepancy still exists following the audit, the Manufacturer or labeler shall justify the reason for the discrepancy or make payment to the Department for any additional amount due.

(b) If there is a discrepancy against the interest of the Manufacturer or labeler in the information provided by the Department to the Manufacturer or labeler regarding

the Manufacturer's or labeler's Rebate, the Manufacturer or labeler, at the Manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the Department. If a discrepancy still exists following the audit, the Department shall justify the reason for the discrepancy or refund to the Manufacturer any excess payment made by the Manufacturer or labeler.

(c) Following the procedures established in paragraph a or b, either the Department or the Manufacturer or labeler may request a hearing before the Department of Human Services Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

(d) The Manufacturer further agrees that the sole and exclusive means for the presentation of any legal claim against the State arising out of this Agreement shall be in accordance with 5 MRSA section 11001. The Manufacturer further covenants not to initiate legal proceedings in any State or Federal court in addition to, or in lieu of, proceedings under section 11001. This Agreement shall be governed in all respects by the laws, statutes, and regulations of the United States of America and of the State of Maine. The Manufacturer consents to personal jurisdiction in the State of Maine.

(e) Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

V. CONFIDENTIALITY PROVISIONS

(a) Commercial or financial information disclosed by the Manufacturer in connection with this Agreement is confidential information, and will not be disclosed by the Commissioner or the Department (including any

auditors or agents thereof) in a form which discloses the identity of a specific Manufacturer or Wholesaler, prices charged for drugs by such Manufacturer or Wholesaler, in accordance with 42 U.S.C. § 1396r-8(b)(3)(D), 22 M.R.S.A. § 402(3) and Maine Rules of Evidence, Rule 507.

(b) The Manufacturer will guarantee the protection and confidentiality of the Utilization Date, including the proper care, custody, use and preservation of records, papers, files, communications of the Department and any other information that may reveal information related to the Utilization Data. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.

(c) Notwithstanding the non-renewal or termination of the Agreement for any reason, the confidentiality provisions will remain in full force and effect.

VI. TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an indefinite period beginning on January 1, 2001.

(b) The Manufacturer may terminate the Agreement for any reason, and such termination shall become effective the first day of the first Calendar Quarter period beginning sixty (60) days after the Manufacturer gives written notice requesting termination.

(c) The Commissioner may terminate the Agreement for any reason, upon sixty- (60) days prior written notice to the Manufacturer.

(d) The termination of this Agreement by either party will not affect any Rebate payments due to the State of Maine.

(e) In the event that any element of this Agreement is affected by a legislative amendment, including, but not limited to the percentage amount of Rebate required, such amended or revised provisions shall be incorporated by reference within this Agreement and shall supersede any of the conflicting provisions of this Agreement. If either party is unwilling to accept such a change in terms, this Agreement may be terminated pursuant to the terms set out in subsections (a) through (d) above.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Commissioner will be sent to:

Maine Rx Program
Director of Pharmacy Programs
Bureau of Medical Services, 3rd Floor
11 State House Station
Augusta, ME 04333-0011

Notice to the Manufacturer will be sent to the address provided to the Department by the Manufacturer.

(b) In the event of a transfer of ownership of the Manufacturer, this Agreement is automatically assigned to the new owner subject to the conditions specified in this Agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision

were eliminated, without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Commissioner under the Constitution, the Social Security Act, other Federal laws or State laws.

(e) The terms "Department: and "Manufacturer" incorporate any contractors or agents thereof, which fulfill responsibilities pursuant to this Agreement unless specifically provided for in the Rebate Agreement.

(f) This Agreement will not be altered except by an amendment in writing signed by both parties and except as indicated in subsection VI (e). No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by a duly appointed representative of the Manufacturer, and the Commissioner, and approved by the Office of the Attorney General.

(g) In the event that a due date falls on a weekend, or a Federal or State holiday, the report or other item will be due on the first business day following that weekend or holiday.

VIII. MANUFACTURER'S ACCEPTANCE

I, _____ hereby agree to the terms
(Name of Authorized Representative)
of this Agreement for the following Manufacturer(s) and labeler(s):

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Signature) (Title)

Date: _____

[Exhibit B]

Maine Rx Program
Draft Proposed Rule for Prior Authorization Provision
9/00

"Drugs of non-participating drug manufacturers shall be reviewed by the Department as to the clinical appropriateness of prior authorization for those drugs. Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and state law. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs."

Maine Medical Assistance Manual, Section 80 (Pharmacy Services)
Draft Proposed Rule for Prior Authorization Provision
9/00

Amend Rule 80.01-7 (new words are underlined).

"Drug Utilization Review Committee means an advisory committee to the Medicaid Program, comprised of physicians and pharmacists, who are licensed to prescribe or dispense medications in Maine."

Propose New Rule:

"The Drug Utilization Review Committee shall consider and make the final determination regarding the clinical appropriateness of all prior authorization recommendations, including those concerning drug manufacturers who do not participate in the Maine Rx Program. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs."

[Exhibit C]

Medicaid Outpatient Prescription Drug Spending

	SFY 97	SFY 98	Chg	SFY 99	Chg
Gross Expenditures	$98,964,628	$109,697,688	10.8%	$135,493,928	23.5%
Drug Rebates	-$17,206,484	-$20,206,046	17.4%	-$27,957,863	38.4%
Net Expenditures	$81,758,144	$89,491,642	9.5%	$107,536,065	20.2%
Drug Rebate Percentage	17.4%	18.4%		20.6%	
Number of Drug Recipients	141,220	144,205	2.1%	148,654	3.1%
Gross Exp Per Recipient	$700.78	$760.71	8.6%	$911.47	19.8%
Net Exp Per Recipient	$578.94	$620.59	7.2%	$723.40	16.6%
Number of Prescriptions	2,793,666	2,870,422	2.7%	3,114,155	8.5%
Prescriptions per Recipient	19.8	19.9	0.6%	20.9	5.2%
Expenditures per Prescription	$35.42	$38.22	7.9%	$43.51	13.8%

November 29, 1999, Christopher Nolan, Bureau of Medical Services, Department of Human Services

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH, of AMERICA — CIVIL ACTION

Plaintiff — Docket No. 00-157 B-H

v

COMMISSIONER, Maine Dept of Human Services

Defendant

Transcript of Proceedings

Hearing on Preliminary Injunction before HON. D. BROCK HORNBY in the United States District Court, Edward T. Gignoux Courthouse, 156 Federal Street, Portland, Maine, on the 19th day of October 2000 as follows:

Appearances:

For the Plaintiff: Bruce C. Gerrity, Esq.
Preti, Flaherty, Beliveau
Allen S. Rugg, Esq
and
Marinn F. Carlson, Esq.
Powell, Goldstein, Frazer & Murphy

For the Defendant: Andrew S. Hagler, Esq.
Attorney General's Office
John Brautigam, Esq.
Cabanne Howard, Esq.

Pauline D. Terry, RPR, CM
Official Court Reporter

Transcript recorded by mechanical stenography, transcript produced by computer aided transcript.

(Transcript of hearing on motion for preliminary injunction before HON. D. BROCK HORNBY in the United States District Court, Edward T. Gignoux U.S. Courthouse, Portland, Maine, on the 19th day of October 2000 beginning at 9:00 AM as follows:)

THE COURT: Good morning. (Counsel responded).

The matter on for hearing is civil number 00-157 P-H, Pharmaceutical Research Manufacturers of America versus the Commissioner of Maine Department Human Services et al. And the matter is on this morning for a hearing on the plaintiff's motion for preliminary injunction. I know there's a wide degree of interest in this case and let me, therefore, just summarize a couple of things that the lawyers already know.

I did hold a telephone conference with the lawyers two days ago, I guess it was, counsel, at my request. The reason for the telephone conference is that the preliminary injunction issue is going based upon affidavits and arguments presented in writing, and the arguments made here this morning. I was inquiring of the lawyers whether it was possible to consolidate into one hearing all of the factual issues that might be present in the lawsuit. That is something that a Federal Court can do under Rule 65, under appropriate circumstances.

As a result of the telephone conference, however, I concluded that it would be premature to do that and so the hearing is going forward on the original premise, which is to say my decision will be based upon the written submissions consistent with the legal arguments, affidavits, legislative materials and things of that sort.

I will also say at the outset that I will not decide the case today. I will hear the arguments. This is a complex matter. I will issue a written decision after I've had the opportunity to digest things I hear this morning. I have read everything submitted. By the way, counsel, I received everything that

each of you submitted in the last day, both the state and the plaintiff, proposed and legislative debate.

The final thing I will say before I hear argument, just an explanation of a couple of terms for the benefit of people in the audience.

I think everyone knows that there are constitutional issues being raised here, and under the federal constitution there is a provision called the Interstate Commerce clause that in Article 1 section 8 of the constitution says, Congress shall have power to regulate commerce with foreign nations, and among the several States, and with the Indian Tribes.

There is a doctrine, and you will probably hear the lawyers refer to it, this is why I want to mention it, called the Dormant Congress Clause. This is a term that only lawyers would understand, that's why I mention it. The theory is, the doctrine is even when Congress does not actually exercise its power to regulate commerce, under Article 1 section 8, that there is a dormant power there which, in some circumstances, even in the absence of regulation, a state cannot threaten that theory, and you will probably hear reference to it in discussion.

The other provision that is at issue is Article 6 of the Constitution that says: This Constitution, and the LAWS of the United States which shall be made in Pursuance thereof, and all Treaties made, or which shall be made, under the authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

That is often called the Supremacy Clause. And there will be argument here today as to whether the Supremacy Clause has any effect on any law.

I just announced that for the benefit of the reporters that might not understand the language being used.

Mr. Gerrity, I will ask you to introduce your co-counsel.

MR. GERRITY: Thank you, your Honor. If I could, I would introduce the Court to Allen Rugg of Powell, Goldstein, Frazier & Murphy. Mr. Rugg will be presenting the oral argument today. With him is Marin Carlson, also of his firm and Daniel Price, who is here as well.

THE COURT: Thank you. Before you start, Mr. Hagler, do you want to introduce your group?

MR. HAGLER: Yes, thank you, your Honor. With me from the attorney general's office is John Brautigam, and also Cab Howard, whom the state is pleased to have join us in these proceedings. I will be arguing the case your Honor.

THE COURT: Thank you. Mr. Rugg, I'll hear you.

MR. RUGG: Thank you very much, your Honor. It is an honor to appear before the Court and we appreciate the Court's scheduling this argument on Pharmaceutical's motion for Preliminary Injunction.

As the Court is aware, the relief that PhRMA is seeking is an immediate Preliminary Injunction restraining the implementation and the enforcement of the Maine Rx program and the related antiprofiteering section of the statute. It is our contention that those statutes violate the constitution with regard to the Commerce Clause, and with regard to the sanction of requiring prior authorization in the unrelated Maine Medicaid program that the statute violates the Supremacy Clause.

Your Honor, the member companies of PhRMA are at immediate risk and will face irreparable injury absent relief from this court. The state is presently implementing this statute. The implementation began on August 2nd, a week before the effective date of the statute.

Presently our member companies have a deadline to respond to the Commissioner's request that they execute rebate agreements by November 1st.

Interestingly, I read in the Wall Street Journal two days ago that Mr. Concannon has announced that after November 1st he intends to take out newspaper ads publicizing the names of companies that have elected not to execute the agreements. We understand that at that time, after November 1st, the companies will be at risk to have their prescription drugs that are distributed to Maine Medicaid recipients subject for the first time to prior authorization.

The record in this case is absolutely unchallenged as to the impact of such prior authorization, on the manufacturers. There is potentially a dispute in this case as to the impact on Medicaid recipients, and I will certainly address that. But for purposes of evaluating the standards for the issuance of a Preliminary Injunction, there is no question that prior authorization will work an immediate irreparable injury to the companies, and I specifically invite the Court's attention to the unchallenged declaration of Dr. Moules from Smith/Kline Beecham.

Let me pause just a moment here. I don't want to misspeak but there are portions of the Moules declaration that are subject to disagreement. When I say that it is undisputed, I'm addressing the portion of his declaration that describes the impact on companies when prior authorization is imposed, and specifically historical data of the impact on market share and sales of four specific drugs.

So, the impact is immediate and it should come as no surprise because when this statute was considered in the legislature, Senator Pingree, and in this legislative history that we just submitted to the Court which just became available to us, Senator Pingree stated if companies do not participate in this program, they will not be able to participate in Medicaid. And that the full, all the tools of the statute will be brought to

bear on companies to compel them to participate in this program.

Commissioner Concannon followed up on that, as I say, a week before the statute even became effective by requesting that the parties immediately execute rebate agreements.

Your Honor, if I may, I would like to address the likelihood of success on the constitutional challenges to the statute. With regard to the Maine Rx rebate, our principal argument, your Honor, is that Maine seeks to regulate out-of-state transactions. I would urge the Court to consider the declaration of Judith Tempel, who is Manager of Distribution Operations of Eli Lilly, that declaration is also unchallenged. Ms. Tempel reports that on August 4th, Ely Lilly in its headquarters in Indianapolis received a letter from Commissioner Concannon. The letter said, "Sign the enclosed rebate agreement. And if you don't, be aware of the antiprofiteering sections of the statute, the prior authorization sanction."

So, when you turn, and this is an exhibit to Ms. Tempel's declaration. When you turn to the proposed rebate agreement, it makes very clear that the state seeks to regulate and receive a payment from Eli Lilly in Indianapolis, Indiana for each prescription pill of Eli Lilly that crosses the counter of a pharmacist here in Maine. That is the only construction possible of the proposed rebate agreement.

I would ask the Court to then consider Ms. Tempel's declaration. Eli Lilly does not manufacture its drugs here in Maine.

It sells its drugs through warehouses in Connecticut, Indiana, and California.

It sells those drugs by distributors and manufacturers coming to Eli Lilly, negotiating arms length purchases of those drugs, which are not identified for shipment to any location in the United States. Pursuant to the agreement

between Lilly and the distributors, title passes at the warehouses, all outside of the State of Maine. And then, finally, the purchaser makes payment to Eli Lilly in Pittsburgh Pennsylvania. What is conspicuous is the absence of any act in this process that occurs in the State of Maine.

The distributors then selling, but the purpose and the effect of the rebate agreement is to change those transactions that occur in Pennsylvania, Indiana and California, changing the economics of Lilly's sales transactions, and taking money out of that transaction and moving it to Maine.

Your Honor, please, we submit that that evidence is unchallenged, uncontroverted and for very good reason.

There is one distributor that does business here in Maine, Bindery Western. A number of our member companies do some business with them, but the vast majority of the prescription medications that are sold here in Maine come to Maine through third-party distributor or wholesale. And we submit to the Court that we believe that's why this portion of our case is uncontroverted by the state. The state realizes that is the true factual record. And then we presume, we will argue to the Court that nevertheless, even though these transactions occur out of state, this statute, for some reason does not directly regulate those transactions.

THE COURT: I'm not sure what you're saying here. Are you saying that it can't apply to Bindery, or whatever that is, but not the others?

MR. RUGG: We think it could. We are submitting to the Court with regard to extraterritoriality argument, we would ask the Court to determine that to the extent that sales occur and are consummated outside the State of Maine, the statute cannot constitutionally regulate those transactions.

THE COURT: Let me press you on that language, outside the State of Maine, you told me, as you characterize it, in the vast majority of cases it's a transaction between a seller and a

distributor both of whom are located outside of Maine and title passes outside of Maine?

MR. RUGG: Yes sir.

THE COURT: You say there are a small portion of cases where a distributor is in Maine, and are you saying that title passes there in Maine? Outside of Maine? Does it matter? What is your contention there?

MR. RUGG: What we are contending is to the extent the transaction is concluded in Maine, if title transfers and the Bindering transaction, if you will, that occurs in Maine, we respectfully submit that our extraterritoriality argument would not attach to those transactions.

Of course, we persist in our contention that the benchmarking problems under the Commerce Clause would still apply to those transactions.

Your Honor, with regard to this extraterritoriality issue, we submit that the legal authorities are clear, that Maine simply has no authority to go beyond its borders to exercise regulation of transactions in other states.

If your Honor please, I would like to turn to the benchmarking argument.

THE COURT: Go ahead.

MR. RUGG: The statute—let me back up. In August when this statute was considered, the clear argument before the senate was the manufacturers would be required to initially provide the Medicaid rebate to Maine residents. That's the force also of Commissioner Concannon' s letter of August 2nd.

The Medicaid rebate amount, under the Medicaid program, is provided by statute. And in general terms, it is the greater of 15.1 percent less than the average manufacturer's price, or the spread between the average manufacturer's price and the manufacturer's best commercial price.

Now, understandably there is a lot of federal regulation but that's the basic formula. What is critical for today's purposes, that is not a statutory number, it is a statutory formula, that is applied on an ongoing basis and is driven by economic market transactions all over the United States. So, if a manufacturer who is participating in Medicaid decides to offer a best price to a commercial customer in Colorado, that affects the Medicaid rebate, Medicaid is a national consensual program, manufacturers make a decision whether they want to participate in Maine Medicaid or whether they want to participate in Medicaid nationwide.

So manufacturers having made that decision understand that market transactions that they enter into affects the Medicaid price.

This statute seeks to exploit that Medicaid calculation for purposes totally unrelated to Medicaid, for the sole purpose of driving down prices of prescription drugs for citizens of Maine. There is no Medicaid interest here, it is simply, you are borrowing the formula and applying it in this state's statute.

What's crucial for the benchmarking analysis is that with this statute, prices in Maine are linked or indexed to prices that are made in market transactions entirely outside of Maine. And we urge the Court to consider the application of *Sealig and Healy* because we think that this statute in effect is quite analogous to the price affirmation statute, for example, that was the subject of the *HEALY* case.

Your Honor, I'd like to turn to the consideration of the sanction of prior authorization.

When we had our telephone conference hearing two days ago we had some discussion of whether there would be issues of fact related to this issue. And our representations to the Court were that we think this is really a legal question. And the legal question, your Honor, I alluded to it earlier, is whether without violating the Supremacy Clause of the

United States Constitution can Maine borrow or take the Medicaid formula and apply it in this case. And if it does, is the vehicle for driving it, namely prior authorization in unrelated programs, consistent with the Supremacy Clause.

THE COURT: I take it by the thrust of your argument that you are agreeing that the publicity requirement alone would not be a sanction that violates the Supremacy Clause.

MR. RUGG: Your Honor, that is correct, we do not contend that that is a violation of the Supremacy Clause.

THE COURT: Or even the Commerce Clause?

MR. RUGG: No, but we think—I'm sorry, to be clear, I agree with the Court. But we think the publicity sanction is important for applying the Preliminary Injunction standard.

THE COURT: I understand.

MR. RUGG: Okay. Your Honor, the nub of the Supremacy argument is that Medicaid prior authorization becomes a tool or a weapon to coerce participation in the Maine program. There can be no mistake that the state recognizes this. When Senator Pingree states, if in fact the manufacturers choose not to cooperate, we will use all the tools available to us here in the State. We will require their participation in this program if they want to participate in the Medicaid program. If they want to participate in the National Medicaid Program, they have to participate in this Maine program. That is what the Senator said, and that is clearly the purpose of the prior authorization sanction in this statute.

And today as we sit here, that is the weapon that is waiving around.

It's the weapon that Commissioner Concannon built August 2 letter.

It is the subject, when he is interviewed in the press, it's the weapon that he invokes.

THE COURT: Whether Senator Pingree said that or not, there is nothing in the statute that takes the manufacturer out of the Medicaid, it is limited to prior authorization if they choose not to comply with the Maine Rx.

MR. RUGG: The statute simply provides that it is not discretionary, that the state shall prior authorize the manufacturer's drugs if they do not participate.

THE COURT: So the question is the bite of that the state

into his provision as—

MR. RUGG: Right. Now, I'm concerned that since, at a very high level we are talking about prescription drugs. We could jump to the conclusion that prior authorization in Medicaid is really quite consistent with prior authorization under the Maine statute.

If your Honor please, let's imagine it's January, next January, and let's assume that certain manufacturers have not participated, for the first time, even though Maine has participated in Medicaid for many years, and has utilized prior authorization for Medicaid purposes, by the force of this statute, manufacturer's drugs are prior authorized for the first time. What has changed?

Has the clinical research changed?

Has the medical literature changed?

Has the assessment of patient need changed?

What has changed is that this statute has become effective and the weapon, the coercive weapon is being brought to bear.

Now, I would like to suggest one other possible way of looking at this. Let's suppose that this statute says that the manufacturer shall make rebate payments, and that the state shall use these rebate payments for elementary school education or for building roads, or dredging the harbor. And

the weapon to coerce this participation is prior submitted authorization.

I think under that scenario there would be no debate as to whether the prior authorization under the Medicaid statute was being used improperly for an unrelated state purpose, and the result being an obstacle and a burden to the realization of the goals of the federal program.

Finally, on this point, we note the declaration by Maine.

The board that will be making these decisions has in the past been making Medicaid decisions. The resources and the personnel who have traditionally implemented Medicaid are suddenly being charged with the responsibility of implementing a very narrow specific state statute.

THE COURT: Let's be precise on the Supremacy—

MR. RUGG: Yes sir.

THE COURT: —argument. Congress has not specifically said this is prohibited, has it?

MR. RUGG: Has not.

THE COURT: So to respond to the attorney general's argument that there are two requirements for prior authorization—

MR. RUGG: Correct.

THE COURT: —being met.

MR. RUGG: That is correct. We do not base this argument on the provision of the Medicaid statute.

THE COURT: What do I have by way of a Chevron type analysis as to whether the Secretary of Health Human Services, or the Health Care Financial Administration or anyone else has given any kind of interpretation?

MR. RUGG: Draft regulations are in the process.

THE COURT: You are referring to state regulations; are you not?

MR. RUGG: Federal.

THE COURT: Tell me about that.

MR. RUGG: I want to be precise, your Honor. My recollection is that the proposed regulations would limit the use of prior authorization for implementation of the Federal Medicaid program but to be absolutely precise, your Honor, I would like to have the ability to follow-up on that.

THE COURT: Actually if you can in writing give me a federal register or citation.

MR. RUGG: We would be happy to.

If I may follow up on the Court's observation, recognizing that the only language in the statute dealing with prior authorization imposes conditions of the use of prior authorization that are of course consistent with its operation of the Medicaid program, I believe its availability of drugs on a 24-hour basis.

The statute does not address the utilization of prior authorization to enforce a totally unrelated statute. And we would submit to the Court perhaps the reason for that is that it would never occur to Congress that a Medicaid statute would be used as the coercive enforcement tool in a totally unrelated purpose. Take my example, if you will, of a program to fund education here in Maine, or roads here in Maine, would you expect the statute to say Medicaid prior authorization cannot be used as a vehicle to enforce contributions to the—fund in Maine. I think the only reason this becomes a narrower issue is, as I said earlier, perhaps at one level one could try to reconcile the federal Medicaid program and the state program as being a consistent common program but these are different populations, different agendas. And what's crucial is the Medicaid program is indeed a national program.

Finally, your Honor, with regard to the likelihood of success on the merits, I'd like to address the antiprofiteering portion of the statute.

THE COURT: Are you going to address the market participation?

MR. RUGG: I would be happy to. Let me do that right now. Our view is that the State of Maine is not participating in this program in a proprietary sense as either a purchaser or seller of drugs. This is classical regulation. The rebate agreement that you saw, Commissioner Concannon sent to Eli Lilly, simply regulates the transaction and the money that is generated from the transaction is then distributed. This is not a state acting in a market place capacity of buying drugs.

Now, we think it could be argued that the state functions as a market participant in the Medicaid program.

We would submit to the Court that that is an entirely different market, different program. We would cite to the Court the Supreme Court case that stands for the proposition that a state may not leverage its power in one market to regulate another one.

THE COURT: What is the case, the Alaska case?

MR. RUGG: Yes sir.

MR. RUGG: With regard to antiprofiteering, clearly today, or maybe speaking more precisely, November 2nd, the companies are at risk to be prosecuted. And the prosecution, it sounds like, would be founded upon their failure to submit to the regulation of the out—of—state transactions in the form of entering into rebate agreements. It's a real risk and the issue is precisely the issue we discussed earlier, the extraterritoriality element.

The failure to submit to the regulation of these foreign transaction exposes companies to that risk.

THE COURT: If it is extraterritoriality, again this is with respect to your argument of what you call the vast majority of the cases but not cases of a distributor in Maine?

MR. RUGG: Right.

THE COURT: Go ahead.

MR. RUGG: The statute makes findings. The state, the legislature has already determined that the manufacturers are in violation of this statute by making statutory findings that the companies charge excessive prices and realize excessive profits. So we have a statute that has made the finding.

We have a statute that imposes a standard of what is profiteering, and we have a statute that provides for immediate power to enforce it through prosecution. Additionally, we are at risk under the Unfair Trade Practices portion of the statute to private litigation over this issue.

Your Honor, I believe I have addressed the likelihood of success on the merits of the constitutional arguments. I would submit to the Court, as I indicated to you two days ago over the telephone, these issues can be decided legally. The facts are not in dispute. The extraterritoriality transactions, the rebate agreement that is indexed to Medicaid, the linkage to the other state transactions, the fact that the companies are compelled to enter into those agreements is not reasonably in dispute. So we submit to the Court that these issues are ripe for decision.

I have already addressed the hardship on the companies that would require the issuance of immediate injunction.

I would like to address the state's interest in avoiding an injunction today.

If you will, the status quo stands to be altered by the effectiveness and the implementation of the statute. There has never been prior authorization of Medicaid drugs for

other state purposes. There has never been the regulation of out—of—state transactions.

There has never been the overt public threat by a public official to run newspaper ads damaging these companies. None of that has occurred historically, it is prospective. The status quo will be preserved by this Court staying the implementation of this statute while the Court has the opportunity to decide these important constitutional issues.

The state cannot in good conscience be heard to argue that it has an interest in the enforcement of a non-constitutional statute.

And I would submit to the Court that we have not heard that from opposing counsel. We don't expect Mr. Hagler will argue to the Court this state has an interest in enforcing an unconstitutional argument. We think he will say the statute is constitutional.

So the real issue here is who will prevail at the end of the day on these critical constitutional issues on whether this statute is constitutional. We submit to the Court that the prudent course is to stay implementation and allow the judicial process to work.

Finally, with regard to the last prong, PUBLIC INTEREST, I don't think I need to belabor that because once again the public in Maine has an interest in its statutes complying with the federal constitution.

We all share that common interest, and that is the compeling public interest.

Your Honor, I would be happy to respond to any other questions the Court might have.

THE COURT: You have not addressed orally one argument that you addressed in writing concerning a third part of the statute which you characterized in writing as RETALIATION.

MR. RUGG: Yes, thank you, your Honor.

The statute, I would respectfully submit, is somewhat vague but we read that provision as saying the companies are compelled to do business in Maine. That if they are doing business in Maine, and because of the threat of this statute, they decided to reorder their business affairs to avoid the regulatory force of this statute, we believe they are at risk under the anti-retaliation provision of this statute. And if that's the case, we submit that it is unconstitutional for a state to enact a statute that compels companies based in Indianapolis Indiana to do business in Maine and to not leave Maine.

THE COURT: But at the moment that is a fairly abstract proposition, is it not, in the sense that I don't know what actions your companies might take to try to avoid Maine legislation. It is conceivable, is it not, that some of their activities might be subject to the statute and others might not? Isn't this a classic case of unripeness for a decision?

MR. RUGG: I understand the Court's concern but it seems that the Court could certainly render a limiting interpretation of the statute such as the Seventh Circuit in the K-S Pharmacy case.

One possible response is for the state to say, of course we don't construe this statute as mandating the continued presence of business operations in Maine. Of course we don't do that because that would be unconstitutional.

If the state does not take that position, we submit to the Court that it would be appropriate and right for the Court to render that type of decision.

Now, there may be further litigation in specific cases down the road that might move that line to apply to other transactions. But at this point we are simply talking about the fairly clear risk of, if a company responds to that statute and

changes its business transactions into another state, is it at risk?

THE COURT: All right, fine, let me find the think I have it.

MR. RUGG: The statutory provision, your Honor?

THE COURT: Yes, the language that refers to manufacturer or distributor or labeler that intentionally prevents limits or lessens or restricts the sale or distribution of prescription drugs in the state. Is that the one?

MR. RUGG: That's the one, your Honor.

THE COURT: All right, thank you, Mr. Rugg, I understand your argument.

MR. RUGG: Thank you very much, your Honor.

THE COURT: Mr. Hagler?

MR. HAGLER: Thank you, your Honor. It is both my duty and honor to argue in favor of this statute and that it is indeed constitutional.

The status quo, and that is what we are here today to decide, is whether the status quo should remain in pending litigation of the constitutionality of the statute, is not good enough. The status quo means that people will remain sick, and will remain unable to afford prescription drugs which they need.

The first test to determine is whether a Preliminary Injunction ought to issue ought to be a balance of the relative harms between the parties. And the state submits that requiring citizens to endure unaffordable drug prices, which is what the result of an injunction preventing implementation of this statute would be, outweighs the harms that are speculated to be the result of the statute by the plaintiffs.

We have cited studies in our papers, your Honor, which indicate that the price of 50 drugs most frequently used by the

elderly increased 4 times the rate of inflation in 1998, that the average price in Maine, the average retail price at the pharmacy for cash transactions in Maine of the 10 most prescribed drugs for the elderly were 86 percent higher at the pharmacy than the price for those same drugs that is charged to the federal government and to the drug companies' most favorite customers in Maine.

When one looks at the five most prescribed for the elderly, that is as high on average as 134 percent.

In the litigation of this case, the state will show that people are choosing not to fill prescriptions that their doctors write because they simply can't afford the price, that people are skipping dosage or splitting pills in a dangerous attempt to economize because they simply cannot afford the price. The public interest which provided the impetus for adopting this statute greatly outweighs the speculative effect on Interstate Commerce that the plaintiffs allege. For that reason we believe that the balance of harms way is in favor of denying the motion for injunction and also that because the state's interest so vastly weighs any speculative purpose on the part of the plaintiff, that the scrutiny on the issue of the likelihood of success on the merits of the case should be applied so that the plaintiffs are forced to prove a strong likelihood of success on the merits of the case. And we submit that this they have not done.

I was intending to address the Commerce Clause argument first, your Honor, but I would like, however, to take up the preemption argument because I think that I can illuminate some of the discussion regarding proposed rules by HCFA, the federal agency which regulates the federal aspects of Medicaid, and the use of a prior authorization in the Maine Rx statute as a mechanism for encouraging participation in that program by applying prior authorizations in the Medicaid program.

And I believe that I have a copy of the appropriate Federal Register and I would be happy with counsel's permission, and the Court's permission, to pass that up and to counsel.

THE COURT: Well you can do that. If you show it to him and he agrees that's fine.

MR. RUGG: Your Honor, may I have just a moment?

THE COURT: Of course.

MR. RUGG: Thank you, your Honor.

MR. RUGG: No objection.

THE COURT: Thank you.

THE COURT: Just so the record is clear, Mr. Hagler has handed me a portion of the Federal Register dated September 19, 1995, concerning proposed rules 42 CSR, 441 and 447. Go ahead.

MR. HAGLER: The federal Medicaid statute is vastly complicated, and as one can see by the number of pages that I have handed up to your Honor, some are proposed rules and comments and answers to comments which surround them. It is my understanding these rules have not been adopted. I will be referring to comments further along in my argument. It is important to recognize that the implementation of a prior authorization requirement in the Medicaid program for any particular drug is not a fait accompli as a result of the adoption of the Maine Rx program.

First, Medicaid establishes the right of the states to use prior authorizations in the Medicaid program. And what a prior authorization requirement is, with respect to a drug, is that a state is free to determine for any particular drug, that that drug should appear on what is called a prior authorization list. And what that means is that if a patient, entitled to receive Medicaid benefits, goes to their doctor, their doctor wishes to prescribe a particular drug, and if that drug appears on the list, then before Medicaid will reimburse the pharmacy

for filling that prescription, the doctor must speak with the state, and the doctor must speak with the state and have access to medical personnel to make the doctor's case that that drug is appropriate for that patient, that is appropriate for that patient because it won't counter act with another substance, another drug the patient might be taking. That it's the appropriate drug because there are no other alternatives which could help the patient with respect to the condition that they suffer, and perhaps even to explain to the state that other drugs were utilized to no effect and; therefore, this is the drug of last resort.

Medicaid requires that if a drug is placed on a prior authorization list, that there be a mechanism so that patients will be assured of getting that drug if they need it.

The Medicaid statutes can also be read such that the decision to place a particular drug on the prior authorization list, and the decision whether to prescribe it, must be governed by notions of medical necessity. But all that the Medicaid statute says about prior authorizations is that states may adopt that requirement in their Medicaid program. And then it says only two other things:

It says if you do have a prior authorization mechanism, there must be a provision for the phone to be answered when the doctor calls within 24 hours.

And there must also be a provision for dispensing on an emergency basis a 3 day suppliable drug which I believe is to cover instances in which the phone is not answered because of a holiday, and that is all the Medicaid statute speaks to.

Congress, therefore, has not affirmatively preempted in expressed language, the use of prior authorizations at all of events with respect to these two provisions. And, in fact, affirmatively granted to 'the states the right to engage in prior authorization.

Now, I would refer the Court and counsel to page 48473.

THE COURT: Go ahead.

MR. HAGLER: Of the federal register that I handed to the Court. And that is the area of the federal Register in which HCFA, the federal agency, is responding to concerns or questions that were received after proposing the rules. And I'm looking at the last column, the third column on the right, and towards the top of that column, the commentator is concerned about 3 things:

One is what if a state were to put on the prior authorization list all drugs of a particular manufacturer, or all drugs of all manufacturers, except the least expensive product in a therapeutic class.

Or—

And I'll skip to the third question. What if a state were to automatically place a prior authorization on the most expensive drug in a therapeutic class without regard to improved outcomes or reduction in total treatment cost associated with that more expensive drug therapy. And the answer of HCFA in construing Medicaid statute is clear, it is found further on down.

HCFA states: We believe that the state should be able to consider both clinical and economic criteria in their prior authorization programs as long as medically necessary drugs are not denied.

That would be okay.

The third question posed in the comments was:

It reads, the drugs if prior authorization—strike that, I'm not going to quote it. It asks—what if states try to get a better Medicaid rebate than the federal Medicaid rebate and used prior authorization, the threat of prior authorization of placing drugs on a prior authorization list, as the incentive to force drug companies to give that better Medicaid rate.

This appears to contemplate that it is possible for states to negotiate better Medicaid rebate for their Medicaid rebate than what the federal government negotiates for them and which otherwise applies across all the states.

This question suggests: What if a state were to say, and if you don't give us a better Medicaid rebate, we are going to consider using prior authorization.

And, again, HCFA says there is no problem with that.

They suggest that states can negotiate separate agreements for additional rebates as long as they comply with the requirements of the statute, and as long as the plan to consider prior authorization insures that patients will receive medically necessary drugs.

The states rules as proposed rules, and they have been proposed and published, as I understand, and we presented them in final form to the Court yesterday. And indeed they do differ in language, in slight variations in language from the form that they took at the time we wrote our briefs but the substance is the same. If a non-participating company, a company that refuses to enter into a Maine Rx rebate program, if they refuse to sign a rebate agreement and refuse to negotiate with the commissioner, the state's D U R committee (Drug Utilization Review Committee) can take off on a drug by drug basis, a decision tree of whether on a drug by drug basis, the drugs of those non-participating companies ought to be placed on that priorauthorization list.

THE COURT: Let me stop for a moment and have you elaborate on a couple of subjects. First of all help me with the Chevron analysis and what you have pointed me to in the Federal Register. You told me, I think, and Mr. Rugg told me of these proposed federal regulations have not been adopted. If that is so, do I have anything here that is authoritative in the Chevron sense on the Supremacy argument, and also can you tell me, do you know anything about why they have not been adopted, and what the status is?

My second question is going to be with respect to state regulations, let's leave it federal at the moment. Can you elaborate on that?

MR. HAGLER: I don't know the reason. I do not believe they were adopted because plaintiff's counsel cited to these in their papers as proposed, and I assume that is correct. And, again, of course these are statements of HCFA interpreting Congress' intent.

THE COURT: My question to you is: When they are still proposed and we have a response to comments but HCFA has not gone forward and adopted, do I have authoritative statements for Chevron purpose?

MR. HAGGLER: I don't know, your Honor, but I would be happy to brief that. I don't know the answer to that.

THE COURT: Let me turn you to the state regulation, your opponent's argument, I think I heard him say on the telephone, perhaps written papers, that the secretary can't rewrite the statute and that that is what he believes is happening here. Would you address that and explain to me what you mean by their decision tree approach as to whether or not an operating manufacturer will have its drugs automatically listed or not listed?

MR. HAGLER: Yes your Honor. First of all the statute states that the department shall adopt prior authorizations, as permitted by law, for companies that don't participate in the Maine Rx program. As permitted by law is the critical phrase and it's the phrase I believe the plaintiff's argument leaves out of the statute.

The commissioner and the department recognize that there is a constraint and it's expressed in HCFA's comments in the Federal Register to implementation of a prior approval, prior authorization process, and that constraint, aside from two examples that Congress put into the statute, is that in all event, or in any event patients entitled to Medicaid

reimbursement must receive drugs which are medically necessary. And the medically necessary determination comes about in two places, it comes about when the doctor calls the pharmacist or the pharmacist working for the state to request prior authorization. And there is always access ultimately to a physician who is employed by the State of Maine, who will make the medical necessity determination.

But it is also, as written in the rules, a guiding principle which the department will endeavor, has expressed an indication and will endeavor to consider, and to consider as the paramount factor in whether on a case by case basis any drug ought to be prior authorized.

THE COURT: Explain that to me. Suppose the XYZ pharmaceutical corporation manufacturer in New Jersey refuses to comply at all with the Maine Rx program and deadlines passes, are all its drugs then listed for prior authorization or are you telling me that there is then a further decision drug by drug of that company as to whether they will be listed or not?

MR. HAGLER: It is the latter.

THE COURT: So conceivably XYZ pharmaceutical of New Jersey, if they completely refuse to cooperate, that the state might conclude all of its drugs are so important that they are not on the prior authorizational list?

MR. HAGLER: That's correct, the hypothetical drug company could have a cure for aids and a cure for cancer that no other drug company has, and to place those drugs on the prior authorization list, because that company did not participate in the Maine Rx program, would have the result, would not be a decision consistent with medical necessity because any time a doctor wanted to prescribe that drug for cancer or HIV, the decision would be yes.

Now, I believe that the rules which affect this, I believe, are found in the pharmacy rules in section 80.05-3.

THE COURT: Say that again?

MR. HAGLER: The easier way, it's the thicker of the green packages and it's on page 8 with the numbers on the bottom, and then it's the second full paragraph on that page.

It reads: Drug Utilization Review.

THE COURT: Yes, I have it.

MR. HAGLER: It says: "The drugs of manufacturers that don't participate in the agreement shall be reviewed by the department as to the clinical appropriateness of prior authorization for those drugs under the Medicaid program.

Well, that implies that if you're going to make a clinical determination you have to do it on a drug by drug basis. Even further, the rule reads:

"Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Review Committee for a final determination of whether those drugs should be prior authorized in accordance with federal and state law. In all instances Medicaid recipients shall be assured access to medically necessary outpatient drug".

There's a similar provision in the Maine Rx rules regarding prior authorization. They are similar because they relate to each other.

THE COURT: I think you mentioned this to me on the telephone but tell me again. What is the ordinary amount of time under state necessary procedure law for public comment and—

MR. HAGLER: Ultimately I believe 40 days, 10 plus 30, and I believe, and I will correct myself after this hearing if I'm wrong but I believe the rules were published yesterday, meaning that notice went out in the paper yesterday and they were being sent to people who had requested them, and I have not calculated what the—

THE COURT: Let me take it one further step. If a broader reading of the statute were too broad and that this interpretation were necessary to preserve the statute on the face of the supremacy challenge, what do I do with the fact that these are still only proposed?

MR. HAGLER: The department didn't believe, and I hope I'm answering your question not with rhetoric, but the department didn't believe that "as permitted by law" in this area, as much as it is interfacing with Medicaid, could mean anything but a requirement that the decision to put a drug on a prior authorization list in Medicaid could be divorced of medical necessity. And so, notwithstanding that the rules are not adopted, I think that the rules in this respect or at least the spirit of these particular provisions is necessary.

THE COURT: I understand, thank you.

MR. HAGLER: Unless your Honor has anymore questions with respect to the preemption argument, turning back for a moment with respect to the Federal Register, the commentary, and this may go to the question that I was unable to answer. The commentary suggests that prior to the enactment of—no, strike that, I can't.

Turning to the Commerce Clause, and again it's important to recognize that in light of the strong state interest in adopting the statute, and the speculative nature of the harms alleged by the plaintiffs, they ought to have to prove that they are going to win almost to a high degree of certainty, likelihood should be in capitals and bold. But nonetheless we believe they have failed under the Commerce Clause argument.

First of all the rebate provision is designed to ensure lower prices for patients in Maine, it is directed towards obtaining lower prices in Maine for drugs and the Supreme Court in the *Brown-Forman* case stated, a state can seek lower prices for its citizens so long as it does not insist that producers or

consumers in other states surrender their relative competitive advantage.

Maine is not asking a consumer or producer in any other state to surrender any advantage that it might have.

Manufacturers are free to negotiate whatever price they want with respect to drugs sold in other states, and the consumers in other states are free and unrestrained by Maine statute to negotiate the best deal that they can. The statute does not co-op advantages enjoyed by those in other states. And for that reason, and for the reason that we have included in our papers, the Seventh Circuit decision in *K-S Pharmacies*, there is no objectionable Interstate Commerce of Maine's rebate program.

THE COURT: I understand your argument that there is no competitive disadvantage but the plaintiff has made two other arguments.

One, the extraterritoriality and the other is benchmark. Hasn't Maine gone outside its borders to control the transaction between the manufacturer and distributor in Kentucky or in Connecticut?

MR. HAGLER: By adopting a federal benchmark?

THE COURT: By providing that when the drugs ultimately end up in Maine that out-of-state manufacturer has to cough up some money to the State of Maine?

MR. HAGLER: The State of Maine is not regulating any transaction.

THE COURT: This is the market participant?

MR. HAGLER: No, your Honor, I make it in both areas. The State of Maine is not regulating any transaction outside of the State of Maine and it is not benchmarking its price to the price that pertains in any other state.

THE COURT: Let's put benchmarking aside for the moment. If XYZ Pharmaceutical company of New Jersey

sells to ABC distributor in Connecticut for $100 and then that drug ends up in Maine to be bought by a Maine consumer, doesn't Maine contemplate that the manufacturer has got to turn over some of that $100 to the State of Maine?

MR. HAGLER: Absolutely not.

THE COURT: And it has not gone outside its borders to regulate? The transaction for which that manufacturer thought it was getting $100 for the sale of that drug turns out to be $50.

MR. HAGLER: No. It has gotten $100 but it has elected to pay a rebate.

THE COURT: You used the word elected, is that important?

MR. HAGLER: If it enters into a rebate agreement, it's required to make the payment. The transaction between the manufacturer and it's out of state distributor remains the same. The plaintiff argues that this is the same as reducing or directly interfering or rewriting the contract which is out-of-state between the wholesaler and the manufacturer. But in *K-S Pharmacy* the Seventh Circuit said that an upstream effect on a wholesale manufacturer impose a have the do under transaction which happens to occur outside of the state which has the statute, does not implicate the Commerce Clause in a way which even requires balancing under the Pipe test.

THE COURT: How is this any different than it may duty on all drugs coming in the State of Maine and proceeds go to the Rx, which I take it Maine cannot the state commerce?

MR. HAGLER: You ask me an interesting question that I don't have a ready answer for it. I don't know that the state could be enjoined from a tax on a motion for Preliminary Injunction.

THE COURT: That may well be under the tax injunction provision. But I'm asking in a constitutional sense.

MR. HAGLER: And I think that if there is no difference, what the Court needs to consider is what the purpose is of what has been labeled as the Dormant Commerce Clause. And the purpose of the Dormant Commerce Clause, as the Supreme Court has articulated that in a variety of cases, is that the state cannot co-op for its self advantages which are in other markets, and Maine has not done that.

THE COURT: Your argument, if I understand from your papers and what you are saying now, the purpose of the Commerce Clause restrictions are to avoid discrimination and there is nothing discriminatory about Maine's statute; is that correct?

MR. HAGGLER: That's correct. And also that the State of Maine is not trying to obtain advantages like in the *Healy* and *Brown-Forman* that inure in other markets for itself. That is slightly different than discriminating from out-of-state and in state transactions. That is not allowing there to be a market occurring in different states throughout the nation that work according to their own competitive advantages. And Maine is not doing that, there is nothing about the rebate which injects Maine into the state of Vermont, or Massachusetts, or New Hampshire.

THE COURT: The other arguments Mr. Rugg has made is the benchmark argument, would you like to address that?

MR. HAGLER: Yes, thank you your Honor. Maine statute does not tie the rebate it seeks to obtain or the rebate it must obtain to the federal rebate. In other words, Commissioner Concannon is authorized by the statute to negotiate with drug companies for a rebate. And the statute does indeed suggest to the commissioner that he should use his best efforts to negotiate a rebate with drug companies that is better than or as good as the rebate which the state gets for those same drugs in the Medicaid program. But we are not tieing the rebate that the Commissioner must receive to that amount.

Now, of course the Commissioner began the negotiations, actually he began negotiations one step in the court of the drug companies because he did not ask for a rebate better than a Medicaid rebate. He submitted a proposal requesting a rebate in the Maine Rx or equal to the federal Medicaid rebate. The statute allows him of course to seek better, but the statute also permits the results that the rebate negotiated between the state and a particular drug company not be the federal benchmark. So, it is not correct to state that Maine is tieing its price or it's rebate in the Maine Rx program to the federal rebate. It is certainly looking to it, but even if it were so that the state were tieing it's rebate to the federal benchmark, again that is not a price that exists, the test of a price, that is not an attempt to obtain for Maine a price that another state was able to negotiate. There is no case of which I'm aware of that says using or even tieing a rebate to a federal benchmark is unconstitutional under the *Healy* and *Brown-Forman* cases. Those cases involve tieing prices in the regulating state with those of a particular state, or with those of the lowest of three bordering states but not an average. And I would submit that the use of an average does not enter in a Commerce Clause.

I will now turn to the market participation argument, your Honor.

Again, plaintiff must show a strong likelihood of succeeding on the merits. There is a complete defense, if you will, that the state has pled and argued in its papers and that is called the market participation exception. And the doctrine that has been developed by the Supreme Court has been that where a state acts as a market participant, actions which might in some fashion interfere with Interstate Commerce or interact or burden the state Interstate Commerce do not, because the state is not regulated, in fact act as market participant. There are two cases which we have pointed your Honor to, *Hughes versus Alexandria Scrap* case and *White versus Massachusetts*, and they are analogous to what Maine

is doing in that, and because in all instances the state is a purchaser.

And in Maine, here Maine purchases a very large quantity of drugs, 100 million dollars of drugs in the Medicaid program. I believe last week I was told the amount of the drugs purchased in the Medicaid program last week were 4 million dollars, just for the week. And last year at the same time the average was about 3 million dollars I believe. So it is an increasing amount and Maine is an important participant in that market, and it is using its market power to attempt to leverage it to obtain lower prices for other constituents in the state.

THE COURT: That's what Mr. Rugg says has gone too far. There is no question Maine is using its market power, given the large scale purchases you have described. And the cases you refer to, for example the White case in Boston who limited its construction projects to firms that employed 90 percent Boston residents, I think. And in the Hughes case, Maryland made it easier for in state owners to sell junk cars—

Mr. Rugg is saying what Maine is doing here, it is trying to use its leverage to effect something else, namely these uninsured-- how do you respond to that?

MR. HAGLER: The *White* case is most instructive because a narrow view—well, Mr. Ruggs says they're not in that market. In White the state of Massachusetts or the city of Boston was in the purchase of construction, they were hiring construction companies. One could argue that they are not in the market of hiring employees, they are in the market of hiring companies to go and build a public works program. But there is a separate market which the City of Boston does not have privity, if you will, in a contract sense, it is not in the market for construction for the employees that those construction companies hire, yet it was able to dictate beyond the purchase of construction contracts where the employees resided and the make up of the work force.

And we would argue the market that Maine is engaged in is the purchase of drugs and it's attempting to use its force to purchase drugs to lower prices for other people whom are in a sense a very closely related to the State of Maine, citizens who don't have drug insurance. And in a sense those other people are potential recipients of Medicaid dollars because if they go to the doctors and they can't afford to purchase the drugs, if they split prescriptions because of the high price, they can't afford them, it's possible they get sicker and are not able to work and find themselves in a situation of becoming eligible to receive Medicaid.

THE COURT: How do you distinguish the Supreme Court decision in the Alaska case?

MR. HAGLER: I argue it is hard to make an analogy to that case because Alaska was selling raw materials and in effect it was saying, further on you can't do something with that raw material, process that raw material in some other state, so vis-a-vis those other processors, and processors in other states, you are discriminating against these states and interstate commerce, that would be another way to distinguish that case.

And finally, your Honor, there's the Pipe balancing test and it is the State's position, and I want to make sure it is clear, that the Court need not get to the Pipe balancing test in order to rule for the state.

As I have argued earlier, we believe that there is no affect on Interstate Commerce, no affect on the rebate program that implicates interstate Commerce laws. But even though there is, again the state's interest vastly exceeds any effect on Interstate Commerce. Again, people are getting sick or getting sicker because they cannot afford their prescription drugs and we believe that when the balance is presented to the Court with facts in this case, that the interest of the state in passing this statute, the interest of its consumers of prescription drugs will so outweigh whatever minimal effect

plaintiff might prove on interstate commerce, and indeed plaintiff's claim that it has an affect on Interstate Commerce, that this statute has an affect on wholesale transaction is unquantified. There is nothing in the record which establishes a link to the size of the harm on Interstate Commerce that plaintiffs don't even flush out in their papers of facts. For that reason I believe that we will ultimately prevail on the Pipe test if the Court gets to that test.

For all of the foregoing reasons, unless your Honor has questions, the injunction ought to be denied.

THE COURT: I have a few questions. First of all does the LCD program have any bearing or does it simply happen to be in the statute, 'low cost for the elderly.

MR. HAGLER: It's another statute like the Maine Rx statute and also like Medicaid which uses the rebate mechanism.

The difference between the drugs for the elderly statute and the Maine Rx statute is that in the drugs for the elderly statute the State of Maine pays a portion, I don't believe all, a portion of the cost of the drugs. And I also believe without federal participation but I might be wrong on that.

THE COURT: It subsidizes?

MR. HAGLER: It's a subsidy, correct.

THE COURT: My second question is as to the anti-profiteering prohibition. You have argued that the rebate program is not extraterritoriality legislation because ultimately the consumer in Maine is ineffective—but if in fact the plaintiffs are correct that the vast majority of the manufacturer's sales distributors are outside the State of Maine, can Maine put a prohibition on the prices that they charge in New Jersey, Connecticut or elsewhere?

MR. HAGLER: I don't know that the statute prohibits—but it's possible. I take what your Honor is getting at is that

we could bring an action against the drug companies for prices which pertain in New Jersey or in some other state. I don't believe that the statute would be so utilized.

THE COURT: Then how would it be utilized? What do you understand to be the significance of that provision?

MR. HAGLER: The problem is, there has not been an investigation as contemplated by the statute. There hasn't been affirmative steps of which I'm aware to institute an action under that statute to flush out the facts. It is difficult enough to deal with the facts on the Preliminary Injunction with respect to the legality of the rebate provision than to contemplate what might occur, and what the facts might be in an action under that provision.

THE COURT: Mr. Rugg tells me the commissioner has alluded to that provision in his negotiating strategy.

MR. HAGLER: I would urge your Honor to read the letter that the commissioner has sent.

THE COURT: I will.

MR. HAGLER: I know how the manufacturer characterized it and how the state would respectfully characterize it as a little bit informative and a little bit bargaining but I don't think it's a threat.

THE COURT: Thank you very much. Mr. Rugg, rebuttal?

MR. RUGG: Yes, your Honor, I'd be happy to start with the LCD program. May I have just a moment?

THE COURT: Yes.

MR. RUGG: Your Honor, the statute makes it mandatory now if you look at the provision of the statute that defines rebate agreement, that is 2681 paragraph 3, it triggers the requirement to participate in a rebate program. I'm not sure that I am precisely answering the Court's question but our argument is that this, it intercepts with the rebate provision of

the statute which is subject to all the constitutional challenges we have been discussing.

THE COURT: I have two questions.

MR. RUGG: Yes sir.

THE COURT: Are you challenging anything concerning the LCD program or can I ignore it or is it not before me?

MR. RUGG: I believe it is not before you.

I have heard an awful lot of lawyers say they only have two questions, at least now I've heard judges can limit themselves to that limitation.

THE COURT: Sometimes.

MR. RUGG: Your Honor, with respect to Mr. Hagler's argument, it started and ended with the issue of how serious the harm is here to the citizens of this state. Drug prices are a serious issue. They are a serious issue that is addressed in all public forms presently, from presidential debates to state houses. We acknowledge the importance of this. It is a national issue. But the remedy that this state has selected, that is most poignantly described by Senator Pingree, is unconstitutional because this state says we can save the misery that our residents are suffering by violating the Constitution of the United States.

I respectfully submit to the Court it is not a proper issue in this case to weigh the hardship of uninsured residents struggling to acquire necessary medications, to weigh that against the constitutional imperatives here.

I would like to address the prior authorization.

We believe, and if the Court would like us to brief this, we would be happy to do so.

We believe that the draft HCFA regulations are informative but are not authoritative, not having been for purposes of a Chevron analysis.

We believe the Court does not have authoritative regulations before it.

What the Court does have is commentary that the state relies on.

You will recall Mr. Hagler saying, characterizing the commentary as what ifs, and responses. Well there are two conclusions.

One is: Clinical decisions should drive prior authorization.

And the second is if we depart from clinical to consider economic, economic is proper within the contents of the Medicaid statute. This state has an interest under the Medicaid statute of maximizing value for medicaid recipients in this state and that is the beginning and the end of that commentary.

We do not contend that the state is going to make prior authorization decisions under the Maine program that will deprive patients of the one drug that they have to have. Mr. Hagler talked about the aids patient or the cancer patient. How about the dozens of antibiotics that are in the market place that prior to enactment of the statute were not subject to prior authorization? But suddenly, with this statute, they are subject to prior authorization for only one reason: To compel participation in the program. And that, your Honor, has nothing to do with the federal program. That is the nub of our argument.

We concede the statute does not say no state shall use prior authorization as a gun to force people to participate in unrelated local programs but it should be self evident.

Your Honor, unless the Court has other questions of me, I thank you very much.

THE COURT: Thank you. Counsel, your arguments have been enormously helpful to me, they were both well prepared and you have presented the case well. Two or three questions

did come up during argument and if either of you want to elaborate briefly on them in the record, or add to your briefs filed originally, I would like to ask them to be filed by Monday. I know that does not give you much time but I know that you also want a decision from me quickly. If there are citations or that you feel you were not able to answer questions I had, then by a brief response I will accept that and I will use it.

Again, I thank you very much, the case has been thoroughly presented and as soon as I have whatever additional submissions, I will proceed to enter a decision as soon as possible. Thank you very much. The Court is in recess.

(Whereupon the Court recessed at 10:33 AM)

CERTIFICATE

I hereby certify the foregoing is a true and accurate transcript of my stenographic notes taken at the time and place herein set forth.

Dated at Portland, Maine this 19th day of October 2000.

/s/
Official Court Reporter

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October 23, 2000

Honorable D. Brock Hornby
Chief U.S. District Judge
United States District Court
156 Federal Street
Portland, ME 04101

Re: *Pharmaceutical Research and Manufacturers of America v. Kevin Concannon, et al.*
Docket No. 00-CV-157-B-H

Dear Judge Hornby:

This letter is submitted in response to your invitation to counsel for the parties, at the close of oral argument on Thursday, October 19, 2000, to address in writing certain issues that arose during that hearing. We appreciate this opportunity and hope that the following clarifications will be of assistance to the Court.

Proposed Regulations of HCFA and the Maine Department of Human Services

The Court raised questions during the hearing concerning the legal significance of (a) the federal Health Care Financing Administration's ("HCFA") proposed regulations implementing the Medicaid prescription drug benefit 60 Fed. Reg. 48,442 (Sept. 19, 1995), and (b) the Maine Department of Human Services' proposed regulations implementing prior authorization under the Maine Rx program, a copy of which was filed with the Court on October 19, 2000.

The Court inquired about the deference due, if any, to HCFA's proposed regulations under the rubric of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Legal precedents confirm that proposed (rather than final) regulations and interpretive commentary are not owed *Chevron* deference. *See e.g., Tedori v. United States*, 211 F.3d 488, 492 & n.13 (9th Cir. 2000) (stating that "proposed regulations carry no more weight than a position advanced on brief") and cases cited therein; *Teweleit v. Hartford Life & Accident Ins. Co.*, 43 F.3d 1005 (5th Cir. 1995) (stating that a regulation never adopted "thus has no precedential authority"). Last term, the Supreme Court indicated that *Chevron* deference is reserved for administrative interpretations formally arrived at "after, for example, a formal adjudication or notice-and-comment rulemaking." *Christensen v. Harris County*, 120 S. Ct. 1655, 1662-63 (2000) (rejecting *Chevron* deference to an interpretation in an opinion letter). Accordingly, PhRMA respectfully suggests that proposed regulations warrant the Court's consideration only to the extent that they are persuasive, *Christensen*, 120 S. Ct. at 1663; no deference is required or appropriate.

It was for their persuasive force that PhRMA's Motion invited the Court's attention to HCFA's proposed regulations, and particularly to HCFA's goal of ensuring that any use of prior authorization has "medical necessity as its *primary* concern." PhRMA Motion at 17-18, discussing 60 Fed. Reg. at 48,454-55 (emphasis added). Maine's new use of prior authorization has the Maine Rx program's funding, not medical necessity for Medicaid patients, as its primary concern. PhRMA maintains that the inconsistency between HCFA's stated goal and that of the Maine Rx program is evidence of the latter's conflict with congressional objectives.

Even as persuasive authority, the HCFA proposed regulations cannot be stretched beyond their logical boundaries. At oral argument, the State referred the Court to

HCFA commentary suggesting that a state could take not only clinical but also economic considerations into account in imposing prior authorization. *See* 60 Fed. Reg. at 48473. HCFA's comments, however, are addressed to economic considerations germane to the Medicaid program, and only the Medicaid program. As HCFA recognized, it is certainly appropriate for state Medicaid authorities to consider economic criteria in prior authorization *for the benefit of the Medicaid program*. But HCFA never suggested that it would be appropriate to consider economic criteria *unrelated to Medicaid*—such as funding non-Medicaid programs like Maine Rx—in imposing prior authorization.

The Court also asked whether draft Maine Rx regulations on prior authorization could cure the statute's infirmities under the Supremacy Clause alleged by PhRMA. PhRMA contends that, whether proposed or final, the Department's regulations cannot save the Maine Rx prior authorization requirement from preemption. The State has not contested that prior authorization imposes a procedural burden on Medicaid doctors and patients, and consumes Medicaid resources (*e.g.* the time and resources of the Medicaid Drug Utilization Review Committee); in fact, the State outlined that burdensome process in some detail at oral argument, *see* Tr. 26-27. PhRMA maintains that the very imposition of that burden, for reasons unrelated to any Medicaid purpose, conflicts with the federal Medicaid program. Regardless of how State regulations implement Maine Rx prior authorization, that burden serves no Medicaid purpose and works to the detriment of the Medicaid program and its beneficiaries. PhRMA respectfully suggests that the State's regulations are of marginal relevance at best, not because they are merely proposed and not final, but because they do not cure the Maine Rx statute's preemption in any event.

Mandatory Participation in the Maine Rx Rebate Program

At oral argument, the State responded to a question from the Court regarding the alleged extraterritoriality of the Maine

Rx rebate program by suggesting that manufacturers would "elect" to pay the rebates. Any suggestion that the Maine Rx program is somehow voluntary simply misperceives the statute. The statute specifically mandates tat manufacturers "*shall* enter into [] rebate agreement[s]" (emphasis supplied) and sets out severe penalties (prior authorization, negative publicity, and profiteering prosecutions) for any manufacturer who does not comply with the statute. Further, the rebate program is not a "negotiation," as the State suggests; the statute does not give manufacturers the option of failing to reach an agreement. Manufacturers thus cannot "elect" not to pay Maine Rx rebates.

Situs of Prescription Drug Sales

Several colloquies with the Court centered on the significance of the situs of manufacturers' prescription drug sales. In connection with its extraterritoriality challenge, PhRMA maintains that sales taking place outside Maine cannot, consistent with the Commerce Clause, be subject to the Maine Rx rebate requirement.

The situs of sales, moreover, relates to the ripeness of PhRMA's challenge to the anti-retaliation provision of the statute: manufacturers are presently precluded from shifting those in-state sales that they do make (if any) to out-of-state distribution channels. The law's interference with the mobility of interstate commerce is especially immediate if the anti-retaliation provision prevents manufacturers from shifting the situs of their in-state sales (if any) to take advantage of a ruling from this Court that the Maine Rx rebate cannot be applied to out-of-state sales.

LCD Program

To clarify our response to a question from the Court regarding Maine's Elderly Low Cost Drug Program, PhRMA confirms that the LCD program is not at issue in its motion for a preliminary injunction, and thus is not before the Court at this time.

We thank the Court for the opportunity to appear before it last week, and for this opportunity to supplement and clarify the record.

Respectfully submitted,

/s/
Bruce C. Gerrity

BCG/rgy
cc: Andrew S. Hagler, Esq.

STATE OF MAINE
DEPARTMENT OF THE ATTORNEY GENERAL
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AUGUSTA, MAINE 04333-0006

October 23, 2000

The Honorable D. Brock Hornby
Chief U.S. District Judge
156 Federal Street
Portland ME 04101

Re: *Pharmaceutical Research v. Concannon, et al.*
Case No.: 00-157-B

Dear Judge Hornby:

We appreciate the opportunity to submit additional briefing on issues raised by the Court but not fully addressed during the hearing of October 19, 2000.

At the hearing the Court asked what might be the effective date of the proposed rules implementing the Maine Rx program. The notice of rulemaking was filed with the Secretary of State on October 10, 2000. Pursuant to the Maine APA, a public announcement was posted in newspapers on October 18. A public hearing is scheduled for Wednesday November 8, 2000, and written comments from the public are due no later than November 20, 2000. The rules can become effective as soon as any responses to the comments and/or minor revisions to the proposed rules are completed, and the review of the Attorney General is obtained. While the ultimate effective date may be as long at 155 days from the public comment deadline, the Department intends to complete the rulemaking process no later than January 1, 2001 so that the rules are in effect when the Maine Rx Program begins.

The remainder of this letter addresses: 1) the application of *Chevron* principles to rules of a federal agency that have been

proposed but not adopted, and 2) whether the Maine Rx Program imposes a "duty."

1. *It Is Unnecessary To Accord Special Deference Under Chevron To The Proposed Rules Promulgated By The Federal Health Care Financing Administration.*

Both parties have called the Court's attention to proposed rules of the Health Care Financing Administration ("HCFA") entitled *Medicaid Program Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers*, 60 Fed. Reg. 48,442 (Sept 19, 1995). In its initial brief, Plaintiff contended that HCFA proposed rules support its contention that the use of prior authorization in the fashion contemplated by the Maine Rx program would defeat Congress's intent to "assur[e] access by Medicaid beneficiaries to prescription drugs where medically necessary." *Plaintiff's Memorandum of Law* at 17.

During the hearing on October 19, defendants cited a different portion of the same proposed rules to demonstrate that HCFA's interpretation actually supports the State's position. First, according to HCFA, "[s]tates should be able to consider both clinical and economic criteria in their prior authorization programs as long as medically necessary drugs are not denied." 60 Fed. Reg. 48,442 at 48,447. Second, HCFA apparently agrees that a State can use its prior authorization power to attempt to negotiate for itself further financial benefits from drug manufacturers beyond those provided by the "national" Medicaid rebates negotiated by HCFA. *Id.*

Maine submits that HCFA agrees with the underlying premise of our preemption argument — that Congress did not intend to impose any requirement on the use of the prior authorization power it gave to the states other than the two, ministerial requirements specifically set forth in the statute. 42 U.S.C. 1396r-8(d)(5). To te extent that the requirement that Medicaid recipients receive "medically necessary" drugs

is viewed as a further restriction on the use of prior authorizations, the Maine Rx statute only authorizes imposition of prior authorization requirement "as permitted by law", and the Department's proposed rules ensure that all medically necessary drugs will be dispensed.

The State does not believe that Congress's intent with respect to prior authorizations is ambiguous. The proposed rules reflect this clarity but it is not necessary to resort to any statement by HCFA to discern Congressional intent. The State cited HCFA's proposed rules primarily to rebut Plaintiffs assertion that the proposed rules require a finding that Congress intended to greatly limit the use of prior authorizations. In short, the question of whether proposed rules, as opposed to *final* rules, are to be afforded deference pursuant to *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), need not be reached. However, if congressional intent were not manifest by the statute itself, HCFA's proposed rules are instructive for the proposition that Congress did not intend to limit use of prior authorizations other than in the limited fashion specifically set forth in the Medicaid statute.

2. *The Rebate Agreement Does Not Constitute A "Duty."*

At the October 19 hearing, the Court asked whether the Maine Rx Program rebates could be compared to an impermissible duty on the importation of drugs.

The Maine Rx Program rebate is not a duty, for several reasons. The rebates do not discriminate against out-of-state goods. The Commissioner is directed to negotiate rebate agreements with all drug manufacturers, irrespective of where the manufacture is located and where its drugs come to Maine from. The Act applies equally to out-of-state drug manufacturers and to any manufacturers which are located in Maine now or in the future. The purpose of the Maine Rx Program is not to discriminate among goods based upon their source. Rather, the rebates are intended to assist the State in

lowering the prices of drugs made by participating manufacturers.

Also, duties, like other taxes, generally apply at a uniform rate across all goods and all taxpayers. Here, however, the Act contemplates negotiation of the rebate by each participating manufacturer. Moreover, not all drugs of a participating manufacturer that enter into the State are subject to a rebate. Instead, only drugs which are ultimately purchased by an uninsured citizen at a pharmacy trigger a rebate payment.

Finally, governments generally enforce the obligation to pay a duty with either criminal or civil sanctions, or by prohibiting the entry of the good. Here, however, the only consequence of failing to negotiate a rebate agreement is the possibility that certain drugs of a manufacturer will be subject to prior authorization requirements before they are reimbursed through the Maine Medicaid program.

For these reasons, rebate payments made pursuant to agreements negotiated between the Commissioner and pharmaceutical manufacturing companies cannot be considered a "duty." As noted at the hearing, however, if the rebate agreement contemplated by the statute is somehow determined to be a form of taxation, the federal district courts lack jurisdiction to grant the requested injunction under the Tax Injunction Act, 28 U.S.C. § 1341.[1]

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[1] Even if the rebate agreements were considered a "tax," the Commerce Clause does not prohibit state taxes that have some extraterritorial reach. In *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977), the Supreme Court determined that a state tax will be sustained so long as it (1) is applied to an activity with a substantial nexus with the taxing state; (2) is fairly apportioned; (3) does not discriminate against interstate commerce; and (4) is fairly related to the benefits received by the taxpaying entity from access to the state. *See also Quill Corp. v. Heitkamp*, 504 U.S. 298 (1992). The *Complete Auto Transit* analysis would necessarily entail considerable factual inquiry in this case. For instance, even though Plaintiff has alleged that very few of its wholesale

Thank you for considering these additional comments.

Very truly yours,

/s/
Andrew S. Hagler
Assistant Attorney General

/s/
John Brautigam
Assitant Attorney General

transactions occur in Maine, it is likely that individual drug manufacturers engage in sufficient sales and promotion activity within the State to satisfy the "substantial nexus" prong of the *Complete Auto Transit* test.

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

PLAINTIFF

v. Civil No. 00-157-B-H

COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, ET AL.,

DEFENDANTS

ORDER ON MOTION TO INTERVENE

On October 26, 2000, I granted a preliminary injunction in favor of the plaintiff against specified parts of Maine's prescription drug pricing legislation. On November 9, 2000, the state defendants appealed. On November 13, 2000, certain would-be intervenors filed a motion to intervene under Fed. R. Civ. P. 24, along with a motion to alter or amend judgment and motion to dismiss Count V of the plaintiff's Complaint. They also requested that I grant them an extension of time, if they are allowed to intervene, to file their own notice of appeal from the preliminary injunction of October 26, 2000. These would-be intervenors have previously participated in the lawsuit by filing an *amicus* brief.

The law on this subject—private plaintiffs attempting to intervene in support of state legislation at the same time the Maine Attorney General is defending the legislation—is well established in this Circuit. *See Daggett v. Comm'n on Gov't Ethics & Election Practices*, 172 F.3d 104, 109-111 (lst Cir. 1999). For intervention as of right, I examine four factors: timeliness; interest in the property or transaction that is the

subject of the lawsuit; effect on ability to protect that interest; and adequacy of representation.

(1) The motion to intervene is timely as to any further proceedings in this trial court because at this point no scheduling order has been entered, no discovery has taken place and the lawsuit is only beginning. It is untimely, however, as to the preliminary injunction issues. Those issues were fully briefed and argued orally following conferences with the Court in preparation for those events. There was abundant opportunity for the intervenors to have moved earlier to intervene. The preliminary injunction has now issued and been appealed and a briefing schedule has been set for the appeal. There is no good excuse for the intervenors not to have moved to intervene earlier if preliminary injunction was their concern.

(2) The would-be intervenors have a distinct and real interest in the lawsuit. Specifically, they are two individuals who cannot otherwise afford needed prescription medication, a membership-based organization that advocates on behalf of Maine's seniors particularly with regard to affordable healthcare, and a family practice physician whose prescription practices are affected by the ability of his patients to pay for medication.

(3) Disposition of this lawsuit will undoubtedly affect dramatically the proposed intervenors' ability to protect their interests because the constitutionality of Maine's attempt to lower the prices for prescription drugs will be determined by the outcome.

(4) As in *Daggett*, the primary issue is adequacy of representation. 172 F.3d at 111 (noting that the "heart of the case" is whether the Attorney General adequately represented their interests). Here, as in *Daggett*, the Attorney General's Office is aggressively defending the statute. Unlike *Daggett*, this statute did not result from a citizen initiative, but is a statute actively supported by the Governor and the

Legislature. The would-be intervenors argue that because their health is at stake the normal presumption in favor of adequate representation by the Attorney General should be reduced. But I do not rely on presumption. The Attorney General is vigorously defending the case, far more than just "adequately." In addition, they point to two arguments they want to make that the Attorney General has not made. The first argument—that the plaintiff is not irreparably harmed—goes only to the preliminary injunction where, I have concluded, the motion to intervene is untimely. The second argument goes to the merits. The intervenors want to argue that the plaintiff has no standing to make its supremacy challenge based upon federal Medicaid law, an argument that the State did not make at the time of preliminary injunction arguments. As in *Daggett*, however, such tactical disagreements are not enough to require intervention as of right automatically. 172 F.3d 104, 112 (1st Cir. 1999). The refusal to present an obvious argument must be "extreme." *Id.* These would-be intervenors can present their argument fully and ably through *"amicus* plus" status, which I now grant them. Unlike factual development, it does not require intervenor status. Moreover, it may well be that the State will see fit to adopt the argument on the merits after the preliminary injunction stage. Lawyers must make tactical and strategic choices as to what arguments to press given the limits of time for oral arguments and page limits for briefs. The fact that a lawyer chooses not to make a particular argument at a given stage does not demonstrate inadequacy of representation. Instead, the record makes abundantly clear that the Attorney General is vigorously defending this legislation with the full support of state government.

Finally, permissive intervention serves no useful purpose here where *amicus* plus status is granted and the Attorney General is representing all the interests of the State in defending the legislation. I make the following Order as I did in *Daggett v. Webster*, 190 F.R.D. 12 (D. Me. 1998).

1. Notice and service of all documents and events shall be given to the would-be intervenors' counsel just as if they were parties in the case.

2. If there are witnesses at trial or deposition where the Attorney General's Office is willing to let the would-be intervenors' lawyer conduct the examination or cross-examination in place of an Assistant Attorney General, that is permitted. What is not permitted is examination or cross-examination by both.

3. I expect that, as appropriate, the Attorney General's Office will take full advantage of any offer of resources, evidence or assistance from the would-be intervenors where to do so will help the Attorney General defend the constitutionality of the statute.

4. Finally, the motion to intervene can be renewed if and when the would-be intervenors have evidence that the case is not being fully and properly presented by the Attorney General.

For these reasons, the motion to intervene is *DENIED* and the motion for extension of time to file a notice of appeal is *DENIED* because I have denied the motion to intervene. No action is necessary on the motion to alter or amend judgment and to dismiss Count V of the plaintiffs Complaint.

SO ORDERED.
DATED THIS *14th* OF DECEMBER, 2000.

/s/

D. Brock Hornby
United States District Judge

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SOCIAL SECURITY ACT § 1927
42 U.S.C. §§ 1396, 1396a(a)(10)(A)-(C), (a)(19), (a)(30)(A)-(B) & (a)(54), 1396c, 1396d(a) & 1396r-8(g)

42 USCA § 1396: Appropriations

For the purpose of enabling each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self- care, there is hereby authorized to be appropriated for each fiscal year a sum sufficient to carry out the purposes of this subchapter. The sums made available under this section shall be used for making payments to States which have submitted, and had approved by the Secretary, State plans for medical assistance.

42 USCA § 1396a: State plans for medical assistance

(a) Contents

A State plan for medical assistance must—

* * * *

(10) provide—

(A) for making medical assistance available, including at least the care and services listed in paragraphs (1) through (5), (17) and (21) of section 1396d(a) of this title, to—

(i) all individuals—

(I) who are receiving aid or assistance under any plan of the State approved under subchapter I, X, XIV, or XVI of this chapter, or part A or part E of subchapter IV of this chapter (including

individuals eligible under this subchapter by reason of section 602(a)(37) 606(h), or 673(b) of this title, or considered by the State to be receiving such aid as authorized under section 682(e)(6) of this title),

(II) with respect to whom supplemental security income benefits are being paid under subchapter XVI of this chapter (or were being paid as of August 22, 1996) and would continue to be paid but for the enactment of that section or who are qualified severely impaired individuals (as defined in section 1396d(q) of this title),

(III) who are qualified pregnant women or children as defined in section 1396d(n) of this title,

(IV) who are described in subparagraph (A) or (B) of subsection (l)(1) of this section and whose family income does not exceed the minimum income level the State is required to establish under subsection (l)(2)(A) of this section for such a family;

(V) who are qualified family members as defined in section 1396d(m)(1) of this title;

(VI) who are described in subparagraph (C) of subsection (l)(1) of this section and whose family income does not exceed the income level the State is required to establish under subsection (l)(2)(B) of this section for such a family, or

(VII) who are described in subparagraph (D) of subsection (l)(1) of this section and whose family income does not exceed the income level the State is required to establish under

subsection (l)(2)(C) of this section for such a family;

(ii) at the option of the State, to any group or groups of individuals described in section 1396d(a) of this title (or, in the case of individuals described in section 1396d(a)(i) of this title, to any reasonable categories of such individuals) who are not individuals described in clause (i) of this subparagraph but—

(I) who meet the income and resources requirements of the appropriate State plan described in clause (i) or the supplemental security income program (as the case may be),

(II) who would meet the income and resources requirements of the appropriate State plan described in clause (i) if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure,

(III) who would be eligible to receive aid under the appropriate State plan described in clause (i) if coverage under such plan was as broad as allowed under Federal law,

(IV) with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them, aid or assistance under the appropriate State plan described in clause (i), supplemental security income benefits under subchapter XVI of this chapter, or a State supplementary payment;

(V) who are in a medical institution for a period of not less than 30 consecutive days (with eligibility by reason of this subclause beginning on the first day of such period), who meet the

resource requirements of the appropriate State plan described in clause (i) or the supplemental security income program, and whose income does not exceed a separate income standard established by the State which is consistent with the limit established under section 1396b(f)(4)(C) of this title,

(VI) who would be eligible under the State plan under this subchapter if they were in a medical institution, with respect to whom there has been a determination that but for the provision of home or community-based services described in subsection (c), (d), or (e) of section 1396n of this title they would require the level of care provided in a hospital, nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan, and who will receive home or community-based services pursuant to a waiver granted by the Secretary under subsection (c), (d), or (e) of section 1396n of this title,

(VII) who would be eligible under the State plan under this subchapter if they were in a medical institution, who are terminally ill, and who will receive hospice care pursuant to a voluntary election described in section 1396d(o) of this title;

(VIII) who is a child described in section 1396d(a)(i) of this title—

(aa) for whom there is in effect an adoption assistance agreement (other than an agreement under part E of subchapter IV of this chapter) between the State and an adoptive parent or parents,

(bb) who the State agency responsible for adoption assistance has determined cannot be placed with adoptive parents without medical assistance because such child has special needs for medical or rehabilitative care, and

(cc) who was eligible for medical assistance under the State plan prior to the adoption assistance agreement being entered into, or who would have been eligible for medical assistance at such time if the eligibility standards and methodologies of the State's foster care program under part E of subchapter IV of this chapter were applied rather than the eligibility standards and methodologies of the State's aid to families with dependent children program under part A of subchapter IV of this chapter;

(IX) who are described in subsection (l)(1) of this section and are not described in clause (i)(IV), clause (i)(VI), or clause (i)(VII);

(X) who are described in subsection (m)(1) of this section;

(XI) who receive only an optional State supplementary payment based on need and paid on a regular basis, equal to the difference between the individual's countable income and the income standard used to determine eligibility for such supplementary payment (with countable income being the income remaining after deductions as established by the State pursuant to standards that may be more restrictive than the standards for supplementary security income benefits under subchapter XVI of this chapter), which are available to all individuals in the State (but which may be based on different income

standards by political subdivision according to cost of living differences), and which are paid by a State that does not have an agreement with the Commissioner of Social Security under section 1382e or 1383c of this title;

(XII) who are described in subsection (z)(1) of this section (relating to certain TB-infected individuals);

(XIII) who are in families whose income is less than 250 percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 9902(2) of this title) applicable to a family of the size involved, and who but for earnings in excess of the limit established under section 1396d(q)(2)(B) of this title, would be considered to be receiving supplemental security income (subject, notwithstanding section 1396o of this title, to payment of premiums or other cost-sharing charges (set on a sliding scale based on income) that the State may determine);

(XIV) who are optional targeted low-income children described in section 1396d(u)(2)(B) of this title;

(XV) who, but for earnings in excess of the limit established under section 1396d(q)(2)(B) of this title, would be considered to be receiving supplemental security income, who is at least 16, but less than 65, years of age, and whose assets, resources, and earned or unearned income (or both) do not exceed such limitations (if any) as the State may establish;

(XVI) who are employed individuals with a medically improved disability described in section 1396d(v)(1) of this title and whose

assets, resources, and earned or unearned income (or both) do not exceed such limitations (if any) as the State may establish, but only if the State provides medical assistance to individuals described in subclause (XV);

(XVII) who are independent foster care adolescents (as defined in section 1396d(w)(1) of this title), or who are within any reasonable categories of such adolescents specified by the State; or

(XVIII) who are described in subsection (aa) (relating to certain breast or cervical cancer patients);

(B) that the medical assistance made available to any individual described in subparagraph (A)—

(i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and

(ii) shall not be less in amount, duration, or scope than the medical assistance made available to individuals not described in subparagraph (A);

(C) that if medical assistance is included for any group of individuals described in section 1396d(a) of this title who are not described in subparagraph (A) or (E), then—

(i) the plan must include a description of (I) the criteria for determining eligibility of individuals in the group for such medical assistance, (II) the amount, duration, and scope of medical assistance made available to individuals in the group, and (III) the single standard to be employed in determining income and resource eligibility for all such groups, and the methodology to be employed in determining such eligibility, which shall be no

more restrictive than the methodology which would be employed under the supplemental security income program in the case of groups consisting of aged, blind, or disabled individuals in a State in which such program is in effect, and which shall be no more restrictive than the methodology which would be employed under the appropriate State plan (described in subparagraph (A)(i)) to which such group is most closely categorically related in the case of other groups;

(ii) the plan must make available medical assistance—

(I) to individuals under the age of 18 who (but for income and resources) would be eligible for medical assistance as an individual described in subparagraph (A)(i), and

(II) to pregnant women, during the course of their pregnancy, who (but for income and resources) would be eligible for medical assistance as an individual described in subparagraph (A);

(iii) such medical assistance must include (I) with respect to children under 18 and individuals entitled to institutional services, ambulatory services, and (II) with respect to pregnant women, prenatal care and delivery services; and

(iv) if such medical assistance includes services in institutions for mental diseases or in an intermediate care facility for the mentally retarded (or both) for any such group, it also must include for all groups covered at least the care and services listed in paragraphs (1) through (5) and (17) of section 1396d(a) of this title or the care and services listed in any 7 of the paragraphs numbered (1) through (24) of such section;

* * * *

(19) provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients;

* * * *

(30)(A) provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area; and

(B) provide, under the program described in subparagraph (A), that—

(i) each admission to a hospital, intermediate care facility for the mentally retarded, or hospital for mental diseases is reviewed or screened in accordance with criteria established by medical and other professional personnel who are not themselves directly responsible for the care of the patient involved, and who do not have a significant financial interest in any such institution and are not, except in the case of a hospital, employed by the institution providing the care involved, and

(ii) the information developed from such review or screening, along with the data obtained from prior reviews of the necessity for admission and

continued stay of patients by such professional personnel, shall be used as the basis for establishing the size and composition of the sample of admissions to be subject to review and evaluation by such personnel, and any such sample may be of any size up to 100 percent of all admissions and must be of sufficient size to serve the purpose of (I) identifying the patterns of care being provided and the changes occurring over time in such patterns so that the need for modification may be ascertained, and (II) subjecting admissions to early or more extensive review where information indicates that such consideration is warranted to a hospital, intermediate care facility for the mentally retarded, or hospital for mental diseases;

* * * *

(54) in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1396r-8(k) of this title), comply with the applicable requirements of section 1396r-8 of this title:

* * * *

42 USCA § 1396c: Operation of State plans

If the Secretary, after reasonable notice and opportunity for hearing to the State agency administering or supervising the administration of the State plan approved under this subchapter, finds—

(1) that the plan has been so changed that it no longer complies with the provisions of section 1396a of this title; or

(2) that in the administration of the plan there is a failure to comply substantially with any such provision;

the Secretary shall notify such State agency that further payments will not be made to the State (or, in his discretion,

that payments will be limited to categories under or parts of the State plan not affected by such failure), until the Secretary is satisfied that there will no longer be any such failure to comply. Until he is so satisfied he shall make no further payments to such State (or shall limit payments to categories under or parts of the State plan not affected by such failure).

42 USCA § 1396d: Definitions

For purposes of this subchapter—

(a) Medical assistance

The term "medical assistance" means payment of part or all of the cost of the following care and services (if provided in or after the third month before the month in which the recipient makes application for assistance or, in the case of medicare cost-sharing with respect to a qualified medicare beneficiary described in subsection (p)(1) of this section, if provided after the month in which the individual becomes such a beneficiary) for individuals, and, with respect to physicians' or dentists' services, at the option of the State, to individuals (other than individuals with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1396a(a)(10)(A) of this title) not receiving aid or assistance under any plan of the State approved under subchapter I, X, XIV, or XVI, or part A of subchapter IV, and with respect to whom supplemental security income benefits are not being paid under subchapter XVI of this chapter, who are—

(i) under the age of 21, or, at the option of the State, under the age of 20, 19, or 18 as the State may choose,

(ii) relatives specified in section 606(b)(1) of this title with whom a child is living if such child is (or would, if

needy, be) a dependent child under part A of subchapter IV of this chapter,

(iii) 65 years of age or older,

(iv) blind, with respect to States eligible to participate in the State plan program established under subchapter XVI of this chapter,

(v) 18 years of age or older and permanently and totally disabled, with respect to States eligible to participate in the State plan program established under subchapter XVI of this chapter,

(vi) persons essential (as described in the second sentence of this subsection) to individuals receiving aid or assistance under State plans approved under subchapter I, X, XIV, or XVI of this chapter,

(vii) blind or disabled as defined in section 1382c of this title, with respect to States not eligible to participate in the State plan program established under subchapter XVI of this chapter,

(viii) pregnant women,

(ix) individuals provided extended benefits under section 1396r-6 of this title,

(x) individuals described in section 1396a(u)(1) of this title,

(xi) individuals described in section 1396a(z)(1) of this title,

(xii) employed individuals with a medically improved disability (as defined in subsection (v)), or

(xiii) individuals described in section 1396a(aa) of this title,

but whose income and resources are insufficient to meet all of such cost—

(1) inpatient hospital services (other than services in an institution for mental diseases);

(2) (A) outpatient hospital services, (B) consistent with State law permitting such services, rural health clinic services (as defined in subsection (l)(1) of this section) and any other ambulatory services which are offered by a rural health clinic (as defined in subsection (l)(1) of this section) and which are otherwise included in the plan, and (C) Federally-qualified health center services (as defined in subsection (l)(2) of this section) and any other ambulatory services offered by a Federally-qualified health center and which are otherwise included in the plan;

(3) other laboratory and X-ray services;

(4) (A) nursing facility services (other than services in an institution for mental diseases) for individuals 21 years of age or older; (B) early and periodic screening, diag-nostic, and treatment services (as defined in subsection (r) of this section) for individuals who are eligible under the plan and are under the age of 21; and (C) family planning services and supplies furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies;

(5) (A) physicians' services furnished by a physician (as defined in section 1395x(r)(1) of this title), whether furnished in the office, the patient's home, a hospital, or a nursing facility, or elsewhere, and (B) medical and surgical services furnished by a dentist (described in section 1395x(r)(2) of this title) to the extent such services may be performed under State law either by a doctor of medicine or by a doctor of dental surgery or dental medicine and would be described in clause (A) if

furnished by a physician (as defined in section 1395x(r)(1) of this title);

(6) medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law;

(7) home health care services;

(8) private duty nursing services;

(9) clinic services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address;

(10) dental services;

(11) physical therapy and related services;

(12) prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select;

(13) other diagnostic, screening, preventive, and rehabilitative services, including any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level;

(14) inpatient hospital services and nursing facility services for individuals 65 years of age or over in an institution for mental diseases;

(15) services in an intermediate care facility for the mentally retarded (other than in an institution for mental diseases) for individuals who are determined, in accordance with section 1396a(a)(31) of this title, to be in need of such care;

(16) effective January 1, 1973, inpatient psychiatric hospital services for individuals under age 21, as defined in subsection (h) of this section;

(17) services furnished by a nurse-midwife (as defined in section 1395x(gg) of this title) which the nurse-midwife is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), whether or not the nurse-midwife is under the super-vision of, or associated with, a physician or other health care provider, and without regard to whether or not the services are performed in the area of management of the care of mothers and babies throughout the maternity cycle;

(18) hospice care (as defined in subsection (o) of this section);

(19) case-management services (as defined in section 1396n(g)(2) of this title) and TB-related services described in section 1396a(z)(2)(F) of this title;

(20) respiratory care services (as defined in section 1396a(e)(9)(C) of this title);

(21) services furnished by a certified pediatric nurse practitioner or certified family nurse practitioner (as defined by the Secretary) which the certified pediatric nurse practitioner or certified family nurse practitioner is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), whether or not the certified pediatric nurse practitioner or certified family nurse practitioner is under the super-

vision of, or associated with, a physician or other health care provider;

(22) home and community care (to the extent allowed and as defined in section 1396t of this title) for functionally disabled elderly individuals; and

(23) community supported living arrangements services (to the extent allowed and as defined in section 1396u of this title);

(24) personal care services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for the mentally retarded, or institution for mental disease that are (A) authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State, (B) provided by an individual who is qualified to provide such services and who is not a member of the individual's family, and (C) furnished in a home or other location;

(25) primary care case management services (as defined in subsection (t) of this section);

(26) services furnished under a PACE program under section 1396u-4 of this title to PACE program eligible individuals enrolled under the program under such section; and

(27) any other medical care, and any other type of remedial care recognized under State law, specified by the Secretary,

except as otherwise provided in paragraph (16), such term does not include—

(A) any such payments with respect to care or services for any individual who is an inmate of a public

institution (except as a patient in a medical institution); or

(B) any such payments with respect to care or services for any individual who has not attained 65 years of age and who is a patient in an institution for mental diseases.

For purposes of clause (vi) of the preceding sentence, a person shall be considered essential to another individual if such person is the spouse of and is living with such individual, the needs of such person are taken into account in determining the amount of aid or assistance furnished to such individual (under a State plan approved under subchapter I, X, XIV, or XVI of this chapter), and such person is determined, under such a State plan, to be essential to the well-being of such individual. The payment described in the first sentence may include expenditures for medicare cost-sharing and for premiums under part B of subchapter XVIII of this chapter for individuals who are eligible for medical assistance under the plan and

(A) are receiving aid or assistance under any plan of the State approved under subchapters I, X, XIV, or XVI of this chapter, or part A of subchapter IV of this chapter, or with respect to whom supplemental security income benefits are being paid under subchapter XVI of this chapter, or

(B) with respect to whom there is being paid a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1396a(a)(10)(A) of this title, and, except in the case of individuals 65 years of age or older and disabled individuals entitled to health insurance benefits under subchapter XVIII of this chapter who are not enrolled under part B of subchapter XVIII of this chapter, other insurance premiums for medical or any other type of remedial care or the cost thereof. No

service (including counseling) shall be excluded from the definition of "medical assistance" solely because it is provided as a treatment service for alcoholism or drug dependency.

* * * *

42 USCA § 1396r-8: Payment for covered outpatient drugs

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(g) Drug use review

(1) In general

(A) In order to meet the requirement of section 1396b(i)(10)(B) of this title, a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information;

(III) the DRUGDEX Information System; and

(IV) American Medical Association Drug Evaluations; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1396b of this title, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1396r of this title, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) Description of program

Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) Prospective drug review

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include

screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over- the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this subchapter by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this subchapter:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this subchapter or caregiver of such individual refuses such consultation.

(B) Retrospective drug use review

The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b(r) of this title) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

(C) Application of standards

The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection[3] (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) Educational program

The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data

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[3] So in original. Probably should be "paragraph."

provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) State drug use review board

(A) Establishment

Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) Membership

The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 * * *[4] licensed and actively practicing pharmacists.

[4] So in original.

(C) Activities

The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section[5] (2)(B).

(ii) Application of standards as defined in section (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

[5] So in original. Probably should be "paragraph."

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) Annual report

Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

* * * *

October 5, 2000

TO: Interested Parties

FROM: /s/Christine Zukas-Lessard/s/, Acting Director, Bureau of Medical Services

SUBJECT: Proposed Rule: Chapter II and Chapter III Section 80, Pharmacy Services, of the Maine Medical Assistance Manual.

Attached, please find a copy of the proposed rules, Chapter II and Chapter III Section 80, Pharmacy Services, of the Maine Medical Assistance Manual.

Revisions to this rule include, but are not limited to, allowing out of state pharmacies to provide certain drugs, requirement of prior authorization consistent with medical necessity for drugs of manufacturers who do not participate in the Maine Rx Program, reduction in maximum supply of non-generic drugs to 34 days, clarification of certain drug coverage provisions, elimination of outdated appendices and elimination of chapter III.

A concise summary of the proposed rule is provided in the Notice of Rulemaking attached to this memo. This notice also provides information regarding the rule-making process. Please address all comments to the agency contact person identified in the attached notice.

Attachment

NOTICE OF AGENCY RULE-MAKING PROPOSAL

AGENCY: Department of Human Services, Bureau of Medical Services

RULE TITLE OR SUBJECT: Chapters II & III, Section 80, Pharmacy Services.

PROPOSED RULE NUMBER:

CONCISE SUMMARY:

Revisions to this rule include, but are not limited to, allowing out of state pharmacies to provide certain drugs, requirement of prior authorization consistent with medical necessity for drugs of manufacturers who do not participate in the Maine Rx Program, reduction in maximum supply of non-generic drugs to 34 days, clarification of certain drug coverage provisions, elimination of outdated appendices and elimination of chapter III.

THIS RULE WILL __ WILL NOT _X_ HAVE A FISCAL IMPACT ON MUNICIPALITIES.

STATUTORY AUTHORITY: 22 M.R.S.A., § 42, § 3173

PUBLIC HEARING:

November 8, 2000 at 3:00 p.m., Kennebec-Penobscot Room, Augusta Civic Center, 76 Community Drive, Augusta, Maine 04330

DEADLINE FOR COMMENTS: November 20, 2000

AGENCY CONTACT PERSON: Marianne Ringel, Comprehensive Health Planner

AGENCY NAME: Policy Development Unit, Bureau of Medical Services

ADDRESS: 11 State House Station
35 Anthony Avenue
Augusta, Maine 04333

TELEPHONE: 207-624-5518
TTY: 1-800-423-4331 or 207-287-1828 (Deaf/Hard of Hearing)

PLEASE APPROVE BOTTOM PORTION OF THIS FORM AND ASSIGN APPROPRIATE MFASIS NUMBER

APPROVED FOR PAYMENT /s/ Marianne Ringel
Authorized Signature

DATE: 10/10/00

FUND	AGENCY	ORG	APP	JOB	OBJT	AMOUNT
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80.01 DEFINITIONS

80.01-1 *Brand-name drug* is defined as a single-source drug, a cross-licensed drug or an innovator drug for which a lower-cost generic equivalent is *not* available.

80.01-2 *Compound Prescription* is any product for which two or more ingredients are extemporaneously mixed in usually accepted therapeutic doses. This requires the pharmacist's skill in weighing, measuring, levigating, etc., at the time of dispensing. The allowable compounding fee applies to the preparation of an individual prescription. It does not apply to prescriptions dispensed from a previously prepared stock supply (i.e.: premixaking a special lotion or ointment in gallons or pounds).

80.01-3 *Controlled Substances* are drugs that come within the scope of the Controlled Substances Act and are divided into five schedules—I, II, III, IV, V.

80.01-4 *Covered Services* are those medically necessary services for which payment can be made under Title XIX by the Department of Human Services.

80.01-5 *Dispensing Practitioner* is a licensed practitioner who, within the scope of his or her license, prepares and dispenses medication, instructs patients to self-administer medication on a regular basis, and is located no less than fifteen miles from a licensed pharmacy.

80.01-6 *Drug Utilization Review* (DUR) means a process designed to ensure that prescriptions shall be appropriate, medically necessary and not likely to result in adverse medical results.

80.01-7 *Drug Utilization Review Committee ~~Board~~* (DUR Committee ~~BOARD~~) means an advisory ~~board~~ committee to the State's Medicaid program, comprised of physicians and pharmacists who are licensed to prescribe or dispense drugs in Maine, ~~to the State's Medicaid program~~.

80.01-8 *Estimated Acquisition Cost* (EAC) is average wholesale price (AWP) minus ten_percent (10%).

80.01-9 *Formulary* is a list of medicines that includes all Legend (prescription) Drugs, to comply with OBRA 90 as amended, except those excluded by these regulations and those over-the-counter drugs listed in Section 80.05-1.

80.01-10 *Generic Drugs* are drugs other than those defined as brand.

80.01-11 *Legend Drug* is a drug bearing the statement "CAUTION: Federal Law Prohibits Dispensing Without A Prescription".

80.01-12 *Maine Maximum Allowable Cost* (MMAC) is the maximum cost allowed by the Maine Department of Human Services for certain multiple source drugs.

80.01-13 *Maximum Allowable Charge* (MAC) is the Federal Uupper Llimit (FUL) established by the federal government for certain prescription drugs. The Medicaid Program reimbursement to a pharmacy may not exceed the MAC for any such drugs.

80.01-14 *New Drugs* are drugs that receive an New Drug Application (NDA) from the Food and Drug Administration after November 1, 1990.

80.01-15 *OBRA 90* Omnibus Budget Reconciliation Act Of 1990 as amended.

80.01-16 *Over-The-Counter Drug* (OTC) is a drug that can be purchased without a prescription.

80.01-17 *Pharmacy Provider* is, for the purposes of determining the proper reimbursement charge, a corporation, association, partnership, or individual that either provides services pursuant to a provider agreement or is related by ownership or control to an entity that provides Medicaid services. This definition of Provider applies only to Section 80, Pharmacy Services, in the Maine Medical Assistance Manual.

80.01-18 *Retail Pharmacy* is a pharmacy which possesses a valid out-patient pharmacy license issued by the Commission of Pharmacy, and which serves Medicaid recipients.

80.01-19 *Usual & Customary Charge* is the reimbursement amount the general public is requested to pay for the goods or services provided.

80.02 ELIGIBILITY FOR CARE

The following recipients are eligible for covered services as set forth in this manual:

A. Categorically Needy Medicaid recipients, whose eligibility is shown on the Medical Eligibility Card as MM, and

B. Medically Needy Medicaid recipients, whose eligibility is shown on the Medical Eligibility Card as MI.

80.03 DURATION OF CARE

Each Title XIX and XXI recipient is eligible for as many covered services as are medically necessary. The

Department reserves the right to request additional information to evaluate medical necessity.

80.04 FORMULARY COMMITTEE

80.04-1 *Purpose*

The purpose of the Formulary Committee, if initiated, will be to establish a formulary for the Maine Medical Assistance Program to identify which prescription and over-the-counter drugs are subject to coverage under the Medicaid Program in compliance with OBRA 90 as amended. The statutory authority to establish a Formulary Committee is found at 22 M.R.S.A. 3174-M.

80.04-2 *Membership*

The Formulary Committee will be appointed by the Director of the Bureau of Medical Services. The committee shall consist of nine members, including three actively practicing pharmacists and three actively practicing physicians. At least one pharmacist shall be a clinical hospital pharmacist. At least one physician shall be a doctor who specializes in infectious diseases, one in primary care, and one in surgery. The pharmacists and physicians shall be Medicaid providers and shall serve for staggered three-year periods of time at the pleasure of the Director of the Bureau of Medical Services.

In addition to the members outlined above, the Director of the Bureau of Medical Services or the Director's designee, as well as the Pharmacy Programs Manager employed by the Bureau of Medical Services, and the Director of the Bureau of Health or the Director's

designee shall serve on the Committee. In addition to the nine voting members outlined above, the Formulary Committee will have at least two non-voting consumer members appointed by the Maine Medicaid Advisory Committee, who shall not be included when determining a two-thirds majority. The committee shall chose a chairperson from among the voting members. A secretary will be appointed by the Director of the Bureau of Medical Services.

80.04-3 *Meetings*

Meetings of the Drug Formulary Committee will be held at the discretion of the Director of the Bureau of Medical Services or the Committee Chairperson upon written petition of one-third of the Committee members.

80.04-4 *Approval of New Drugs*

Drugs will be added to the formulary, and will be deleted from the formulary, only upon a two-thirds vote of the Formulary Committee, the procedure for which is described in Section 80.04-5. When a new drug does not meet the two-thirds vote for approval to be added to the formulary, requests for such drugs shall be reviewed on an Authorization Prior to Provision (APTP) basis as outlined in Section 80.07-3.

80.04-5 *Formulary Policy and Procedures*

A. Drugs will be considered for addition to the formulary in one of four ways:

1. By the Formulary Committee, on the basis of evidence of sufficient requests for the drug through the APTP process

outlined in Section 80.07-3 to justify consideration for addition to the formulary. The Bureau of Medical Services may also request consideration of drugs based on the volume of inquiries received.

2. The Committee may initiate consideration of over-the-counter (OTC) drugs, since such drugs are not generally approved through the APTP process.

3. The Committee may also, through an on-going review of the formulary by therapeutic class, identify areas which are deficient or areas of possible deletion or restriction.

4. The drug manufacturer may initiate consideration of drugs for which there will be no fiscal impact as defined herein.

B. The steps to be followed for consideration by the Committee for the addition of drugs to the formulary is as follows:

1. The Ppharmacy Pprograms Mmanager will prepare material for distribution to Committee members commenting on efficacy, therapeutic benefits, and current peer reviewed literature.

   The Committee will arrange for specialty providers, as appropriate, to comment on this written material. The Ppharmacy Pprograms Mmanager shall classify the drug(s) under consideration into one of three categories, described below, which shall trigger a predetermined procedure. The Committee shall review that

determination and after review of the available material, may change the determination by a two-thirds majority vote of those members present.

Category A:

Therapeutic benefit and no projected fiscal impact. No therapeutic benefit and no projected fiscal impact.

Approval for drugs with no fiscal impact as defined herein shall be submitted to the next meeting of the Formulary Committee and shall be automatically recommended for addition to the formulary. No projected fiscal impact is defined as follows:

Reimbursement for the drug at the lowest adult daily dose for the primary indication will be compared to the average of the costs of the lowest adult daily dose for drugs within the same class, weighted by utilization for each drug within that class for the prior quarter. No consideration should be given to recommended course of therapy, improved, compliance, etc., for drugs in this category.

For combination drugs, the billed amount should be less than the combined prices of its components to have no fiscal impact.

Category B:

Therapeutic benefit and a projected fiscal impact.

Therapeutic benefit is defined as a clinically (not pharmacologically) more effective drug and/or a less toxic drug than alternative therapies currently on the formulary. A drug for which the sole advantage is convenience or compliance is not considered to have a therapeutic benefit.

Therapeutic benefit will be addressed by the clinician assigned the particular drug through his or her review with a final determination made by the Committee.

Drugs with an estimated fiscal impact shall normally be added to the formulary only in one of two ways:

a. a specific appropriation of funds from the legislature with approval of the Governor or

b. a deletion of other drugs forom the formulary to maintain budget neutrality.

The therapeutic benefit of the drug being considered should be weighed against the therapeutic benefit of drugs already on the formulary. If the value of the drug under consideration is not thought to be great enough to justify an offsetting deletion and if no funds are appropriated for the addition, the drug shall be put on a pending list of drugs to be added to the formulary once funds become available.

Category C:

No therapeutic benefit and a projected fiscal impact.

Drugs which are determined to be of no therapeutic benefit which have a projected fiscal impact shall not be added to the formulary. Such drugs would be available only through the APTP process to the extent necessary for a specific individual.

2. At the conclusion of discussion of all drugs being considered at a meeting, the Committee members shall record their vote for each drug on a form to be supplied at each meeting. The Chairperson will tally the votes and announce the Committee's preliminary determination. Written documentation of the vote will be kept on file at the Bureau of Medical Services.

3. The Department shall promulgate as a rule any additions or deletions to the formulary. After any hearing or comment period has expired, the Committee shall review any comments and take a final vote on the addition or deletion of any drugs. Any preliminary or final determination by the Committee requires a two-thirds majority vote of the members present. Inclusion of a drug on the formulary will automatically include all conventional dosage forms of that drug, with the exception of transdermal systems, sustained release and injectable dosage forms, unless specifically approved by The Formulary Committee.

4. All drugs added to the formulary will be referred to the Drug Utilization Review Committee (DUR) for monitoring.

80.05 COVERED SERVICES

80.05-1 *Drug Benefits*

Reimbursement is available for the following medically necessary drugs:

A. *Legend drugs.* All Llegend drugs found on the Maine Medical Assistance Program formulary, except those drugs set forth in Section 80.05-3, which must meet the requirements of APTP, and those drugs set forth in Section 80.05-4, which are covered for certain diagnoses only as set forth in that section. In addition, those legend drugs described as a non-covered service in Section 80.06 are not reimbursable.

B. *Over-the-Counter (OTC) drugs.* The following over-the-counter drugs and supplies when filled pursuant to a prescription:

Insulin, needles and syringes, urine or blood test strips* for diabetes, artificial tears or ophthalmic lubricants, oral iron for salts, calcium salts, except oyster shell source which is only covered for certain diagnoses (~~see~~See 80.05-54, G and F), diphenhydramine, quinine sulfate, nicotinic acid (niacin), meclizine, ~~and~~ permethrin, prenatal vitamins as described in (C) and smoking cessation aids.

* Strips used in conjunction with meters or electronic testing equipment are a Durable Medical Equipment item (Chapter II Section 60).

C. *Prenatal vitamins*, and OTC, prenatal vitamins for pregnancy and up to three months postpartum only and in quantities of one hundred only with no more than three refills. Reimbursement for prenatal vitamins is

usually for generic vitamins only. If the requesting physician wishes a particular brand, he or she must write "medically necessary" on the prescription.

D. Legend drugs that become available as over-the-counter drugs are eligible for reimbursement, by prescription only, if such coverage is cost effective and recommended for coverage by the Drug Utilization Review Committee, even if some brand name Products remain as Legend drugs.

~~D~~E. Reimbursement for drugs may be denied for the following reasons:

1. Utilization. If the Department in conjunction with the DUR board believes a drug is being generally overutilized or abused, it may choose to restrict that drug if other existing drugs are available to treat the problem.

2. Cost Containment. The Department may deny coverage for any drug that represents an excessive cost to the Medicaid program without correspondingly wide use by Medicaid recipients.

3. Cost Effectiveness. The Department may deny coverage for any drug if existing drugs available would treat the condition for less cost.

80.05-2. *Compound Prescriptions*

Reimbursement may be made for a compound prescription when the Department determines that the compound prescription contains at least one ingredient that is a legend drug, present in a therapeutic quantity, and

obtainable in effective strength only by prescription. A compound prescription which contains a laxative, stool softener, vitamin, antacid or cough and cold preparation and is prescribed solely to circumvent these Medicaid reimbursement limitations is not covered. Compound prescriptions containing a DESI drug (less than effective) are not covered. All active ~~ACTIVE~~ Ingredients contained in a compound prescription must be covered under ~~the R~~ a rebate ~~Program~~ agreement with the Maine Medicaid Program.

80.05-3. *Drug Utilization Review*

Drugs of manufacturers that do not participate in a rebate agreement for the Maine Rx program shall be reviewed by the Department as to the clinical appropriateness of prior authorization for those drugs under the Medicaid Program. Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Review Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and state law. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs.

80.05-~~4~~3. *Drugs That Require Authorization Prior to Provision (APTP)*

In addition to those drugs requiring prior authorization under Section 80.05-3, Tthe following drugs require APTP as described in Section 80.07-3 and must be supplied in the appropriate generic form if available:

A. Brand name controlled substance drugs listed on the Ffederal Uupper Llimits or MMAC list except for brand name methylphenidate, which only requires the physician to write "medically necessary" on the prescription. These drugs will only be approved for physician documented treatment failure.

B. Over-the-counter (OTC) drugs, including OTC vitamins and vitamin combinations, all OTC and legend laxatives and/or stool softeners. These items will be approved only when the prescriber can demonstrate, with supported medical justification, their cost effectiveness and that the use of these drugs is medically necessary for effective care of the patient. NOTE: These items are furnished by a nursing facility or ICF-MR and are included in the per diem rate of reimbursement for residents of these facilities.

C. Single entity dietary vitamins in prescription strengths only when used for a documented vitamin deficiency or prophylaxis to prevent such deficiency. Other uses, including but not limited to cosmetic purposes, are not a covered service. For the purposes of this section, vitamin K and dihydrotachysterol are not considered dietary vitamins.

D. The following drugs will be reimbursed only for the medical conditions described below. These will only be paid at the Medicaid Pharmacy rate using the NDC code and unit.

1. a. Total enteral nutrition to sustain the complete nutritional needs for recipients using nasogastric, gastrostomy or jejunostomy tubes.

b. Specified nutritional support products for patients who are:

~~i~~i. Currently malnourished: A Subjective Global Assessment (SGA) must be completed and submitted for risk assessment/documentation (see Appendix #3) before prior authorization can be considered.

~~ii~~ii. At significant risk for malnourishment secondary to an underlying medical condition. Documentation of medical condition must be submitted before prior authorization can be considered. A Subjective Global Assessment (SGA) may be requested.

Prior to consideration for authorization, the client's physician must supply the following additional documentation in writing: A description of the attempts made to employ other oral measures to correct the risk/condition; supplement used; time frame of use; reason for failure. Documentation that other oral measures are contraindicated and the reason why must also be submitted.

Prior authorization is effective for up to ~~six~~ twelve (12~~6~~) months as determined by medical criteria and documentation of ongoing medical necessity. ~~If use is required beyond six (6) months, updated medical documentation of ongoing medical necessity will again be required for prior authorization.~~

Medicaid will not cover specified nutritional support products as part or all of a voluntary weight loss program.

2. Lactulose, and its analogs, for recipients with portal encephalopathy or cirrhosis or as a laxative with written documentation from a physician of treatment failure with use of standard laxative therapy and demonstrated cost effectiveness.

3. ~~TB~~ Ddrugs for the treatment of tuberculosis when authorized by the Bureau of Health (see 80.06 (H)).

E. Drugs not found on the formulary or drugs not described as a covered service in Section 80.05 will be approved, in compliance with OBRA 90, only where no other drugs found on the formulary or otherwise reimbursed by the Maine Medicaid Program will adequately treat the condition presented or where only a new drug not found on the formulary will prevent a higher and more costly level of care.

F. Filling of Insulin syringes by Pharmacy Providers. This service will be approved only when the prescriber can demonstrate, with documented medical justification cost effectiveness and that the use of this service is medically necessary for effective care of the patient. (See 80.09(F)(1)(b)(iv)

G. Other Drugs. Additional drugs may be prior authorized as recommended by the Medicaid DUR Committee. Prescribers will be notified by quarterly mailings and the BMS website. In all instances Medicaid recipients shall be assured access to all medically necessary outpatient drugs.

80.05-54 *Drugs Covered for Certain Diagnoses Only*

Reimbursement for the following drugs will be made only for the conditions (diagnoses) described and only when the prescriber has written the diagnosis on the prescription. For a patient living in a nursing facility or an ICF-MR the diagnosis must only be noted in the patient's chart. To the extent that any of the drugs listed in this subsection (80.05-5) would require prior authorization under 80.05-43, such prior authorization is not necessary:

A. Methylphenidate and dextroamphetamine for attention deficit disorders or narcolepsy only.

B. Legend Cough & Cold Preparations and Decongestants for Sinusitis, Otitis Media, Emphysema or Asthma only.

C. B-12 for Documented Pernicious Anemia or Megaloblastic Anemia only.

D. Aspirin, Buffered Aspirin, Enteric Coated Aspirin and Acetaminophen for arthritis only and in quantities of 250, 500 or 1000 only.

E. Multi-vitamins and Vitamin E for cystic fibrosis.

F. The following oral drugs are covered for chronic renal failure, renal transplant recipients and dialysis:

Aluminum Carbonate Gel, Aluminum Hydroxide, Bisacodyl, B Vitamins with C, Calcium products including Calcium Oyster Shell, Calcitriol, Calcifediol, DHT (Dihydrotachysterol), Docusate Calcium, Docusate Sodium, Docusate w/Casanthranol, Ergocalciferol 50,000u, iron containing

products, Magaldrate; Multi-vitamins with 1mg. Folic Acid, Phosphorous replacement products, Psyllium Hydrophilic M ucilloid, Senna, Thiamin.

G. The following drugs are covered for recipients with quadriplegia and paraplegia:

Antacids, Ascorbic Acid, Bisacodyl, Calcium Oyster Shell, Docusate w/Casanthranol, Docusate Potassium, Docusate Sodium, Fleet Enemas, Glycerin Suppositories, Lubricating Jelly, Mineral Oil, Multivitamins, Povidone iodine gel, Psyllium Hydrophilic Mucilloid, Senna, Stress Vitamins, and Vitamin C & D.

~~The above drugs are not a Medicaid benefit under this Section in nursing facilities or ICFs MR if the produce is listed as part of the per diem rate of reimbursement in Chapter II, Section 67 "Nursing Facility Services" or as defined in Section 50.06-9 "ICF MR Services" or as defined in Section 60.04-4, "Medical Supplies and Durable Medical Equipment" of the Maine Agreement Manual or as defined in Attachments A or B of the Agreement between the Department and a Boarding Home.~~

80.06 NON-COVERED SERVICES

The following drugs are not reimbursed by the Medicaid Program:

A Anorexic, or certain weight loss drugs.

B Vitamins and vitamin combinations (except ~~generic~~ prenatal vitamins as allowed under 80.05-1(C) ~~during pregnancy and three months post partum~~ and vitamins covered for dialysis and recipients with quadriplegia and paraplegia or when the criteria in Section 80.05-3(B) and Section 80.05-4(E) is met).

C Laxatives and laxative combinations and stool softeners and stool softener combinations (except when the criteria in Section 80.05-3(B) is met.)

D Hexachlorophene scrubs for nursing facility patients.

E Products listed as part of the per diem rate of reimbursement in Chapter II, Section 67 "Nursing Facility Services" or as defined in Section 50.06-9 "ICF-MR Services" or as defined in Section 60.04-4, "Medical Supplies and Durable Medical Equipment" of the Maine Medical Assistance Manual or as defined in Attachments A or B of the Agreement between the Department and a residential care facility.

~~Needles and syringes for nursing home patients.~~

F Drugs discontinued or recalled by the manufacturers.

G Less than Effective Drugs as defined by the Food and Drug Administration (a list is available from the Bureau of Medical Services). These drugs are not covered under the Medicaid State plan, therefore, these drugs will not be deducted from a nursing facility resident's assessment.

H Drugs prescribed for TB (these are normally available from the Bureau of Health's Tuberculosis Program free of charge). Medicaid coverage is only available after referral from the Bureau of Health and Medicaid prior authorization.

I Legend drugs that become available as over-the-counter drugs are not eligible for reimbursement even if some brand name products remain as legend drugs.

J Over-the-counter drugs except drugs listed in 80.05-1(B) and when the criteria in Section 80.05-3 are ~~is~~ met.

K Any drug that is for experimental use or prescribed for indications other than those approved under OBRA 90 guidelines or have no Food and Drug Administration (FDA) sanctioned or approved indications.

L Drugs not covered under OBRA 90 as amended.

M Cosmetic agents. Ex.: Retin-A when used for wrinkles, Rogaine for hair growth.

N Drugs of manufacturers not participating in the Rebate Program.

O Fertility d~~D~~rugs.

P Nutritional support products as part or all of a voluntary weight loss program.

80.07 POLICIES AND PROCEDURES

80.07-1 *Regulation of Pricing*

Drugs added and deleted and price changes with regard to drugs which fall within the parameters of the Federal Upper Limits Program will be updated upon notification from the United States Government Health Care Financinge Administration.

Price changes with regard to drugs which fall within the MMAC guidelines and all other Medicaid drug benefits will be updated according to periodic ~~manual~~ review by the P~~p~~harmacy P~~p~~rograms M~~m~~anager of fluctuations in the average wholesale price list maintained by the Department of Human Services, Bureau of Medical Services under the guidelines of OBRA 90 as amended.

Designation of an effective date for all such changes will be determined together with allowance for mailing requirements in order to

afford a minimum thirty day notice to the provider.

80.07-2 *Standards of Participation*

A. A pharmacy provider must be duly licensed or certified by the appropriate regulatory body in the state in which it is located. An out-of-state provider may participate and receive payment for dispensed drugs only if the recipient has been injured or suffers a disease or illness while temporarily absent from Maine. The Maine Medicaid Program ~~State~~ will only reimburse drugs dispensed by out-of-state providers on an emergency basis. ~~Chronic or maintenance drugs are not a benefit in such cases.~~ Exceptions to this requirement are 1) for those out-of-state pharmacies located in towns within fifteen miles of the Maine-New Hampshire border, or five miles of the Maine-Canada border, that provide regular services to Maine recipients; ~~or~~ 2) those pharmacies which provide drugs for foster care children or other recipients that permanently reside in other states and are wards of the State of Maine; or 3) out of state pharmacies appropriately licensed or registered with the Maine Board of Pharmacy, satisfying prior authorization requirements and standards for quality of care to Medicaid beneficiaries as established by the Bureau of Medical Services and only for the provision of the following specialty medications:

1. Growth hormones
2. Antihemophilic factors
3. Intravenous Immune Globulin drugs (IVIG)

4. Drugs for the prevention of Respiratory Syncitial Virus (RSV)
5. Miscellaneous drugs not subject to the OBRA 90 rebate program requirements as authorized by the Bureau.

B. ~~Effective May 31, 1991, a~~A pharmacy provider will receive reimbursement only for drugs supplied by manufacturers who comply with the rebate requirements of the Health Care Financinge Administration in accordance with ~~the Omnibus Budget Reconciliation Act of 1990~~ (OBRA '90). If a pharmacy does not have a drug available that is provided by a manufacturer/labeler who complies with the rebate requirement of HCFA in conformance with OBRA 90, the pharmacist must directly and individually inform the individual of other pharmacies that may carry the drug. Additionally, drugs that are otherwise covered by Medicaid but are provided from manufacturers/labelers not covered under the rebate agreement may be subject to prior authorization requirements upon thirty days written notice from the Bureau. (See 80.04-5 for prior authorization policy.)

~~B~~C. Any pharmacist or dispensing practitioner, whether in State or out of State, who wishes to submit claims for payment must submit an application for participation to the Bureau of Medical Services, Provider File Unit~~Division of Medical Claims Review~~. The Bureau will review the application and notify the submitting provider whether or not he or she is accepted as a provider and if accepted, the effective date. An application may be denied, terminated or not renewed for any of the

grounds set forth in Maine Medical Assistance Manual, Chapter I. An accepted application must be on file before any reimbursement for any item or service will be made.

80.07-3 *Authorization Prior to Provision (APTP)*

A. The procedure for all drugs requiring APTP is as follows:

All prior authorization requests shall be made in writing and include the following:

1. Recipient name, Medicaid identification number and birthdate.
2. Patient diagnosis, prognosis and other pertinent information.
3. List of other drugs currently prescribed for the patient.
4. Name of drug(s) requested, the National Drug Code (NDC), and the medical justification for the request, including the reasons why other reimbursable drugs are not adequate to treat the condition presented.
5. Requesting prescriber's name, address, signature and telephone number.
6. Name and address of pharmacy where drug(s) are to be obtained.
7. Requests for APTP must be sent to: Pharmacy~~Drug~~ Program Coordinator, 11 State House Station, Augusta, Maine 04333-0011.
8. When the request is received, it will be reviewed and a determination

made concerning whether or not the drug will be added as a limited benefit for the recipient according to the standards set forth in Section 80.05-3. A completed prior authorization request will be responded to within 24 hours. If a request is approved, it is valid for a maximum of one year, at which time a new prior authorization is required.

Prior authorization shall be given retroactively if it is determined by the prescriber that an emergency requires that the drug be dispensed immediately for the patient's well being. However, the Bureau's Pharmacy Programs Manager or his or her representative must be contacted at 287-1818, or 1-800-321-5557 for a verbal authorization.

If not available at that time, the Pharmacy Programs Manager or his or her representative ~~MUST BE CONTACTED ON THE FIRST WORKING DAY THEREAFTER~~ must be contacted on the first working day thereafter.

Following any verbal authorization, the prescriber must make the request in writing and must include a description and justification of the emergency, following the procedure discussed above and the standards set forth in Section Reimbursement for such drugs. shall continue pending written Departmental action.

80.07-4 *Weekend and Holiday Authorization Prior to Provision*

A. When a drug requires APTP and the Bureau of Medical Services is closed, a pharmacist or dispensing practitioner may request APTP by

contacting the agent authorized by the Bureau of Medical Services. The staff shall review and respond to APTP requests and provide verbal approval when appropriate. Any APTP requests for recipients whose medical needs cannot wait until the Bureau of Medical Services' offices are open, shall be made by calling the authorized agent.

NOTE: list of authorized agents will be provided by the Bureau of Medical Services.

B. All APTP requests made after 3:00 PM the day before the Bureau of Medical Services' offices are closed and before 8:00 AM the day the Bureau of Medical Services' office reopens,' shall be responded to by the authorized agent. All APTP requests that receive verbal approval shall be followed with written documentation, as defined in Section 80.07, from the prescriber within seven (7) days from the date of verbal approval. All written documentation shall be submitted to:

Pharmacy~~Drug~~ Program Coordinator
Bureau of Medical Services
~~Professional Claims Review Unit~~
11 State House Station /249 Western Ave.
Augusta, Maine 04333-0011
- OR - fax 28~~7~~-8601~~2675~~

C. All non-immediate APTP requests shall be submitted to the address listed above.~~:~~

~~Drug Program Coordinator~~
~~Bureau of Medical Services~~
~~Professional Claims Review Unit~~
~~11 State House Station /249 Western Ave.~~
~~Augusta, Maine 04333-0011~~
~~- OR - fax 287-2675~~

~~C~~D. Only when the prescriber is unable to reach the ~~State~~Bureau of Medical Services or the authorized agent for prior authorization, a minimum of a 72-hour supply shall be provided to the recipient except for controlled substances, brand named MAC drugs, and any drug that cannot be reimbursed under existing State and Federal Regulations.

80.07-5 *Dispensing Practices*

Compliance with the following dispensing policies is required:

A. Dispensing practices must be in accordance with the best medical, pharmaceutical and economical practice.

B. Generic drugs as rated A in the current edition of the FDA Orange Book must be dispensed in accordance with State law, if available at a lower cost than the brand name product, unless the practitioner writes the words "Medically Necessary" in his/her own handwriting on the face of the prescription or the prescriber's order sheet for institutionalized patients. Nothing other than the prescriber's own handwritten statement is acceptable. The printed box on the form or order form that could be checked by the prescriber to indicate that a name brand is necessary is not acceptable. (See 80.09-E)

C. Single source or co-licensed d~~D~~rugs must be dispensed in quantities not to exceed a 34 day supply. FDA A-rated generic drugs must be dispensed in quantities sufficient to effect optimum economy (normally not less than a one-month supply nor more than a three-month supply for maintenance medications for

chronic illness). ~~Pharmacist~~Providers will not be reimbursed for split prescriptions. Also see 80.09-(C).

D. For the classes of maintenance therapy listed below, a minimum of one month's (thirty days) supply must be supplied except when the prescriber's written orders are to the contrary or it is the initial filling of the prescription. Drugs in ointment or cream form must be dispensed in the largest tube available when used for maintenance therapy, except in the initial filling of the prescription.

1. Analgesics
2. Antianemia drugs
3. Anti-emetics
4. Antihistamines
5. Barbiturates
6. Cardiovascular drugs
7. Dermatologicals
8. Diuretics
9. Hormones
10. Hypnotics
11. Psychotherapeutic agents
12. Sedatives
13. Spasmolytics
14. Sulfonamides
15. Hypertensive drugs
16. Tranquilizers
17. Drugs for Parkinson's disease

18. Anti-epileptic drugs
19. Peripheral vasodilators
20. Antiarthritic drugs

E. All prescriptions must be dispensed within thirty days of the date prescribed.

F. Payment for medications dispensed in quantities in lesser or greater amounts than therapeutically reasonable may be withheld pending contact with the prescriber to determine justification for the amount.

G. All prenatal vitamins must be dispensed in quantities of one hundred with no more than three refills.

H. Aspirin and acetaminophen must be dispensed in quantities of 250, 500 or 1000 only.

I. ~~*Pharmacis Affiliated with Hospitals, Boarding Homes and/or Nursing Homes.*~~

A pharmacy affiliated through common ownership or control with a hospital, ~~boarding~~ home, ICF-MR, private nonmedical institution, residential care facility and/or nursing home is allowed to dispense Medicaid covered ~~Medicaid~~ prescription drugs to Medicaid recipients in that facility. The drugs must be dispensed by a registered pharmacist, according to dispensing regulations. Drugs are to be billed in a manner consistent with the Department's billing guidelines and drug claim processing system (see Section 80.09) without professional fee.

J. ~~*Dispensing Practitioners*~~

Practitioners who have been authorized to dispense drugs for Medicaid patients shall not

receive a dispensing fee, but will be allowed to charge the co-pay amount in addition to the acquisition cost of drugs dispensed. Records of all such dispensing must be available for review and audit.

A participating pharmacist must maintain the original copy of all prescriptions for which payment from the Medical Assistance Program is requested. The original prescription shall be either a hard copy generated by a computer, written by the prescriber, or reduced to writing when received by the pharmacist by telephone. Information required by the Maine State Board of Pharmacy shall be recorded on each prescription and must include name of patient, name of drug, quantity ordered, directions, name of prescriber, date written and initials of pharmacist filling prescription. A record of each refill must be kept on the prescription or on the profile or be available on a computer.

80.07-6 *Refills*

Reimbursement for refills will be made only if the following conditions are met:

A. The prescription authorizes refills.

B. No more than one year has passed since the date of the original issue. Reimbursement for a drug later than one year from the date of original issue requires a new prescription, subject to the limitations described in Section 80, Pharmacy Services, subsection 80.07-5 Dispensing Practices.

C. Reimbursement will be made for refills dispensed in no less than a thirty-day supply

for chronic conditions except when the prescriber specifically directs otherwise.

D. ~~Reimbursement will not be made for amounts dispensed in more that a thirty-day supply~~ Single source or co-licensed drugs must be dispensed in quantities not to exceed a 34-day supply. FDA A-rated generic drugs must be dispensed in quantities sufficient to effect optimum economy (normally not less than a one-month supply nor more than a three-month supply for maintenance medications for chronic illness). Providers will not be reimbursed for split prescriptions. ~~(except for chronic illness) unless the recipient will be out of state and will not return before a refill is needed~~. See section 80.07-5(c).

E. Refills shall be mailed to the recipient upon request.

80.07-7 *Pharmacist's Responsibility*

The Department supports generally-accepted professional judgments made by pharmacists, including the right to refuse to dispense any prescription which appears to be improperly executed or unsafe, based on the pharmacist's professional judgment. The Department expects that any pharmacist who suspects that a recipient may be inappropriately using a drug will report the recipient to the Pharmacy Programs Manager or to the Director, Surveillance and Utilization Review Unit, Bureau of Medical Services, 11 State House Station, 35 Anthony Ave., Augusta, Maine 04333-0011.

80.07-8 *Recipient Restriction Program*

One of the purposes of the Recipient Restriction Program (See Chapter IV in this Manual) is to decrease and control over-utilization or abuse of Medicaid reimbursed services and benefits and to minimize medically unnecessary and potentially addictive drug use.

Restricted recipients are issued Medical eligibility cards that identify their authorized health care providers. Providers not listed on the cards will not be reimbursed for their services unless they were furnished in emergencies or with prior approval from the Division of Surveillance and Utilization Review.

For additional information, please see Chapter IV, Recipient Restriction Program. ~~and Chapter II Section 80.07 of the Maine Medical Assistance Manual.~~

A recipient may appeal a decision concerning this program to the Commissioner of the Department of Human Services in accordance with appeal procedures described in Chapter I of the Maine Medical Assistance Manual.

80.07-9 *Surveillance and Utilization Review*

Surveillance and Utilization review requirements are delineated in Chapter I of the Maine Medical Assistance Manual.

~~A. The Division of Surveillance and Utilization Review monitors the medical services provided and determines the appropriateness and necessity of the services.~~

~~B. The Department and its professional advisors regard the maintenance of adequate treatment and service records as essential in substantiating the delivery of quality care. In addition, providers should be aware that treatment and service records are key documents used for post-payment reviews. In the absence of proper and complete records, no payment will be made and payments previously made may be recovered in accordance with Chapter I of the Maine Medical Assistan e Manual.~~

~~C. Upon request, the provider must furnish to the Department, without additional charge, the records, or copies therof, corresponding to and substantiating services billed by that provider.~~

~~D. The Department expects that records or other pertinent information will be transferred, upon request and with the patient's signed release of information, to other clinicians involved in the patient's care.~~

80.08 CO-PAYMENT

A. A co-payment is to be charged by the pharmacy to each Medicaid recipient for each prescription filled or refilled except as specified in Section 80.08-2. The amount of the co-payment shall not exceed $2 per generic drug and $3 per brand-name drug according to the following schedule:

Medicaid Payment for Rx		*Recipient Co-payment*
$10.00 or less		$ .50
$10.01 -25.00		$1.00
$25.01 - 50.00	for generic drugs	$2.00
$50.01 or more	for brand-name drugs	$3.00

B. No pharmacy may discount the co-payment for promotional purposes. The pharmacy shall not deny pharmacy services to a Medicaid recipient on account of the recipient's inability to pay a co-payment.

Providers must rely upon the recipient's representation that he or she does not have the cash available to pay the co-payment. However, the individual's inability to pay does not eliminate his or her liability for the co-payment.

C. If a recipient is dispensed a drug in a quantity specifically intended by the prescriber or pharmacist to last less than one month for the recipient's health and welfare, only one co-payment for that drug that month is required.

D. Copayment exemptions and dispute resolution procedures are described in Chapter I of the Maine Medical Assistance Manual.

~~80.08-2 *Co-payment Exemptions*~~

~~No co-payment may be imposed with respect to the following services:~~

~~A. Family planning services and supplies;~~

~~B. Services furnished to individuals under twenty-one (21) years of age;~~

~~C. Services furnished to individual who is an inpatient in a hospital, skilled nursing facility, nursing facility, ICF-MR or other medical institution, if that individual is required, as a condition of receiving services in that institution, to spend for costs of medical care all but a minimal amount of his or her income required for personal needs.~~

~~D. Services furnished to pregnant women, including services provided during the three months following the end of a pregnancy;~~

~~E. Emergency services, i.e., when failure to provide the service could reasonably be expected to:~~

~~1) place the recipient's health in serious jeopardy;~~

~~2) cause serious impairment to bodily functions, or~~

~~3) cause serious dysfunction of any bodily organ or part.~~

~~F. Services furnished to an individual of a health maintenance organization in which he or she is enrolled.~~

~~G. Recipients in State custody.~~

~~H. Services furnished to any individual who is a resident of a boarding home or a foster home;~~

~~Medicaid recipients exempt from co-payment requirements are identified by a "NO" in the co-payment column on the recipient's Medical Eligibility Card.~~

~~80.08-3 *Co-payment Limitation*~~

~~If a recipient is dispensed a drug in a quantity specifically intended by the prescriber or pharmacist to last less than one month for the recipient's health and welfare, only one co-payment for that drug that month is required.~~

~~80.08-4 *Co-payment Disputes*~~

~~If a recipient believes that he or she is exempt from a co-payment, disputes the amount of the co-payment, or has been denied a service for~~

~~failure to make a co-payment, he or she may contact the Department for assistance in resolving that dispute. Complaints should be directed to the Assistant Director, Bureau of Medical Services at 287-2674.~~

80.09 REIMBURSEMENT

Medicaid reimbursement for drugs covered under this Section will only be made for drugs of any manufacturer that has entered into and complies with a rebate agreement and specific reporting requirements as defined by Title 19 of the Social Security Act Section 1927 described in OBRA 90 as amended.

A. The amount of payment for services requested and rendered shall be the lowest of the following:

1. The usual and customary charge or any amount the provider will accept from any other third party program or from the public in the form of discounts, special rebates, incentives, coupons, club plans or contracts with the exception of senior citizen discounts; or
2. The estimated acquisition cost (EAC) plus $3.35 professional fee except as stated in Section 80.07(5)(I).
3. The Federal Upper Limit (FUL) or the Maine maximum allowable cost (MMAC) plus $3.35 professional fee except as stated in Section 80.07(5)(I).
4. Maximum reimbursement shall be at average wholesale price (AWP) minus seven and one-half percent (71/2%) for those pharmacies servicing nursing facilities, private non-medical institutions, ICFs-MR and residential care facility ~~boarding homes~~ for which the dispensing program bills Maine Medicaid for:

a. only the actual doses administered with one dispensing fee per drug per month; and

b. the program results in no drugs subject to return for credit as described in Section 80.09(H).

The co-payment specified in Chapter II, Section 80.08 "Co-payment" of the Maine Medical Assistance Manual will then be deducted from the amount reimbursed.

The Department will ~~periodically~~ notify pharmacies of updates to ~~publish a~~ lists of drugs and their prices covered by FUL or MMAC and a full copy can be provided upon request to the Bureau of Medical Services.

B In accordance with Chapter I, of the Maine Medical Assistance Manual, it is the responsibility of the provider to seek payment from every other source except the Low Cost Drugs for the Elderly Program (DEL).

It is the responsibility of the provider to verify a patient's eligibility for medical assistance prior to providing services by requesting the individual to present his or her Medical Eligibility Card on each occasion that a service is provided and verifying this information as described in Chapter 1 of the MMAM.

C. If a recipient's eligibility is due to expire within one month of the date of service, reimbursement will only be made for up to a one-month's supply.

D. State Maximum Allowable Cost (MMAC)

The establishment of a MMAC is subject, but not limited, to the following considerations:

1. Multiple manufacturers;

2. Broad wholesale price span;

3. Availability of drugs to retailers at the selected cost;

4. High volume of Medicaid recipient utilization;

5. Bioequivalence or interchangeability.

E. Reimbursement for Drugs More Expensive Than MAC or MMAC Allowances

A prescriber who requests a drug more expensive than a MAC or MMAC limited drug must certify its need in writing with the words "medically necessary" on the prescription or, for institutionalized patients, on the prescriber's orders. The printed box on the prescription blank that could be checked by the prescriber to indicate that a name brand is necessary is not acceptable. Nothing other than the prescriber's own handwritten statement on the prescription or the prescriber's order will be accepted.

Note: This does not apply to drugs more expensive than MAC, MMAC limited drugs that are controlled substances (Classes II, III, IV, V). For these drugs, prior authorization must be requested by the prescriber. The prescriber must submit objective medical evidence showing a treatment failure of the generic drug (See Section 80.05-3), except for Methylphenidate which only requires "Medically Necessary" in the physician's handwriting on the prescription.

F. Reimbursement for Compounded Drugs

Reimbursement for these drugs is determined by subtracting the co-payment described in Section 80.08, from the sum of the professional fee and the ingredient cost.

1. Professional fees for compound drugs are as follows:

a. Submitted by paper claim form:

(~~1~~i) $3.35 for an amount dispensed from a stock supply, or for solutions or lotions involving no weighing.

(~~2~~ii) $5.35 for compounding handmade suppositories, powder papers, capsules and tablet triturates and for mixing home TPN hyperalimentation.

(~~3~~iii) $4.35 for compounding ointments and for solutions or lotions involving weighing one or more ingredients and mixing home intravenous (IV) solutions.

b. Submitted electronically: **

(~~1~~i) $3.10 for an amount dispensed from a stock supply, or for solutions or lotions involving no weighing, for all claims electronically submitted for verification, eligibility, adjudication, ProDur edits, and payment.

(~~2~~ii) $5.10 for compounding handmade suppositories, powder papers, capsules and tablet triturates and for mixing home TPN hyperalimentation, for all claims electronically submitted for verification, eligibility, adjudication, ProDur edits, and payment.

(iii) $4.10 for compounding ointments and for solutions or lotions involving weighing one or more ingredients and mixing home intravenous (IV)

solutions, for all claims electronically submitted for verification, eligibility, adjudication, ProDur edits, and payment.

(iv) $12.50 for filling insulin syringes for a maximum 14-day supply for all claims electronically submitted for verification, eligibility, adjudication, ProDur edits, and payment.

** Effective with dates of service on or after *July 23, 1998*.

2. The ingredient cost is the sum of the cost of the defined ingredients contained in the compound drug. For any ingredients that cost twenty-five cents or less, twenty-five cents is the allowed charge.

G. Reimbursement for Prenatal Vitamins:

Reimbursement for prenatal vitamins is for generic vitamins only. If the requesting physician wishes a particular brand, he or she must write "medically necessary" on the prescription.

H. All drugs dispensed to patients in nursing facilities, ICFs-MR, and residential care facility ~~boarding homes~~ shall be dispensed in thirty-day supplies except for Schedule II narcotics not used for maintenance therapy. Schedule II items may be dispensed in lesser days supply if therapeutically and financially reasonable or to comply with the institution's stop order policies. Drugs in ointment form shall normally be dispensed in the largest size available.

1. All ~~FULL OR PARTIAL UNIT DOSE~~ full or partial unit dose or modified unit dose ~~MODIFIED UNIT DOSE~~ drugs except the

following shall be returned to the pharmacy for credit if they are in a reusable condition.

a. Liquids and ointments, unless sealed packages are unopened,

b. Class II controlled drugs.

2. Instructions for Return

a. Institutions will complete Pharmaceutical Control Sheet (MCMA 45) columns 1 through 7.

b. Institutions will distribute copies of the completed form in the following manner:

Send green and yellow sheets with listed medication to servicing pharmacy;

Retain blue sheet for nursing home files;

Return white copy to:

Drug Program Coordinator
Professional Claims Review Unit
11 State House, Station
Augusta, Maine 04333

c. Pharmacies will calculate the unit price and total value (columns 8 and 9), total each sheet, and return the green copy to the Drug Program Coordinator at the above address. The Department will total all sheets and charge back 70% of the value, allowing the servicing pharmacy 30% for work involved. These forms should be sent promptly and at least monthly. Medication not returned to a pharmacy for credit shall be destroyed in the nursing or boarding facility and witnessed by two persons who must then sign the MCMA 45.

80.010 BILLING INSTRUCTIONS

A. Manual ~~B~~billing must be accomplished in accordance with the Department's Billing requirements, per the "Billing Instructions for Pharmacy Services".

B. Electronic billing must be accomplished in accordance with the Department's billing requirements per the Electronic Media Claims rider to the provider enrollment agreement.

~~B. In order to receive full Medicaid reimbursement for claims submitted for a service that is defined as an exemption in Section 80.08-3 (Co-Pay Limitation), please use a "C" indicator in block 6 of the original claim form. A dash must be used to avoid keying errors (ex. 123456-C). On refill claim forms, please put a "C" after the Rx number.~~

October 5, 2000

TO: Interested Parties

FROM: /s/Christine Zukas-Lessard/s/, Acting Director, Bureau of Medical Services

SUBJECT: Proposed Rule: Rules of the Department of Human Services, Chapter 130, Section 1, Maine Rx Program.

Attached, please find a copy of the proposed rule, Chapter 130, Section 1, Maine Rx Program, of the Rules of the Department of Human Services.

This new rule implements the legislatively mandated Maine Rx Program. The program allows Maine residents enrolled in the Program to purchase drugs at reduced cost.

A concise summary of the proposed rule is provided in the Notice of Rulemaking attached to this memo. This notice also provides information regarding the rule-making process. Please address all comments to the agency contact person identified in the attached notice.

Attachment

NOTICE OF AGENCY RULE-MAKING PROPOSAL

AGENCY: Department of Human Services, Bureau of Medical Services

RULE TITLE OR SUBJECT: Rules of the Department of Human Services, Chapter 130, Section 1, Maine Rx Program

PROPOSED RULE NUMBER:

CONCISE SUMMARY:

This new rule implements the legislatively mandated Maine Rx Program. The program allows Maine residents enrolled in the Program to purchase drugs at reduced cost.

THIS RULE WILL ___ WILL NOT _X_ HAVE A FISCAL IMPACT ON MUNICIPALITIES.

STATUTORY AUTHORITY: 22 M.R.S.A., § 254-B

PUBLIC HEARING:

November 8, 2000 at 1:00 p.m., Kennebec-Penobscot Room, Augusta Civic Center, 76 Community Drive, Augusta, Maine 04330

DEADLINE FOR COMMENTS: November 20, 2000

AGENCY CONTACT PERSON: Marianne Ringel, Comprehensive Health Planner

AGENCY NAME: Policy Development Unit, Bureau of Medical Services

ADDRESS: 11 State House Station
35 Anthony Avenue
Augusta, Maine 04333

TELEPHONE: 207-624-5518
TTY: 1-800-423-4331
or 207-287-1828
(Deaf/Hard of Hearing)

PLEASE APPROVE BOTTOM PORTION OF THIS FORM AND ASSIGN APPROPRIATE MFASIS NUMBER

APPROVED FOR PAYMENT /s/
Authorized Signature

DATE: 10/10/00

FUND	AGENCY	ORG	APP	JOB	OBJT	AMOUNT
010	10A	3010	012			

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1. Authority

The Maine Rx Program is authorized by, and these regulations are issued under, the authority of 22 MRSA Chapter 603. The Commissioner of the Department of Human Services has delegated the responsibility for administration of the Program to the Bureau of Medical Services.

2. Definitions

Department means Department of Human Services.

Participating Pharmacy means a retail pharmacy located in this State, or another business licensed to dispense prescription drugs in this State, that has signed a Maine Rx Agreement.

Average Wholesale Price means the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.

Labeler means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.

National Drug Code (NDC) is the identifying number maintained by the Food and Drug Administration.

3. Program Eligibility

In order to be eligible to participate in the Maine Rx Program, the participant must be a resident of the State of Maine. Under existing Maine Board of Pharmacy rules, a pharmacy must have a current address on file for a patient when a prescription is filled. For purposes of this Chapter, this existing record-keeping requirement verifies residency. Eligibility may be subject to verification through audit. Enrollment applications may be obtained at local DHS offices, town offices, hospitals,

health care providers, pharmacies and other designated locations.

4. Maine Rx Enrollment Card

Each eligible participant in the Maine Rx Program will be issued an eligibility card. The Department or its authorized agent will issue a permanent card to each enrollee in the Maine Rx Program. The permanent card will be issued by mail only to a Maine address.

5. Duration of Eligibility

Applicants remain eligible until the applicant is no longer a resident of the State of Maine. The enrollee is responsible for notifying the Department within 30 days of the event that makes him or her ineligible.

The Department reserves the right to deny to or terminate eligibility for individuals who engage in fraud or abuse.

There is no ceiling on frequency, total number, or cost of the prescriptions filled for an individual participant.

6. Appeal of Denial of Eligibility

Whenever an individual has been denied eligibility to this Program, or had his or her eligibility terminated he or she may appeal the decision pursuant to the Administrative Procedures Act as described in the member handbook.

7. Pharmacy Participation

A. Any pharmacy that wishes to submit claims for payment under the Maine Rx Program must be a pharmacy located in Maine, or another business licensed to dispense prescription drugs in this State.

B. An application for participation in the Maine Rx Program must be submitted and approved by the Department for all participating pharmacies.

C. Requirements for pharmacies that are approved for participation in the Program include, but are not limited to the following:

1. Immediate written notification to the Department of any change in any of the information which the pharmacy previously submitted to the Department;

2. Non-interference with the recipient's freedom of choice in seeking medical care or services from any institution, agency, pharmacy, or person who is qualified to perform a required service;

3. Provision of services and supplies to recipients in full compliance with Title VI of the Civil Rights Act of 1964, which prohibits discrimination on the grounds of race, color, or national origin, and also on the basis of religious beliefs, sex, or handicapping conditions;

4. Provision of services and supplies to recipients in this Program which are of the same quality and mode of delivery as are provided to the general public. Participating pharmacies are required to provide services and supplies to Program recipients from manufacturers who participate in the drug rebate program for the Maine Rx Program;

5. Maintenance and retention of business and professional records sufficient to document fully and accurately the nature, scope and details of the drugs and services provided. These records must be saved for five (5) years, or for a period of time not less than that required by the Health Care Financing Administration, whichever is less. However, if an audit is initiated within the required retention period, the records must be retained until the audit is completed;

6. Furnishing to the Department, in the form and manner requested, pertinent information regarding services for which charges are made;

7. Holding confidential, and using for authorized Program purposes only, all medical information; and

8. Compliance with the requirements of applicable Federal and State laws, including the provisions of the statute and regulations establishing this Program, and not engaging in a practice that is prohibited by applicable Federal and State laws, or Program regulations.

D. There shall be no cost imposed by the Department to the pharmacy for submitting claims or participating in this Program.

The pharmacy reserves the right to decline to dispense any prescription which appears to be improperly executed and/or which in the professional judgment of the pharmacist is unsafe as presented, or may be harmful if not monitored.

8. Termination of Pharmacy Participation

The participating pharmacy may terminate his or her participation in the Maine Rx Program at any time. Written notification of voluntary termination is to be made to the Bureau of Medical Services. A termination notice is effective when received by the Department. When a termination notice is sent to the pharmacy by the Department, it is effective thirty (30) days after receipt of the notice by the pharmacy.

9. Appeals

Any pharmacy that is aggrieved by a decision made pursuant to this policy has thirty (30) calendar days from the date of receipt of that decision to request an informal

review, in writing to the Director of the Bureau of Medical Services. This review will be conducted by the Director of the Bureau, or a designee who was not involved in the decision under review. A written report of the decision resulting from that review will be issued to the pharmacy.

If the pharmacy is dissatisfied with the informal review decision, an administrative hearing may be requested by writing to the Commissioner of the Department of Human Services within thirty (30) days from the date of receipt of the Director's report. The appeal process under the Maine Rx Program, for all pharmacy providers, whether or not participating in the Medicaid Program, is identical to the appeal process under the Maine Medicaid Program. See Chapter I of the Maine Medical Assistance Manual for more details on provider appeals.

10. Drugs Provided

A. Coverage and reimbursement under the Maine RX Program will only be made for drugs from those manufacturers or labelers with a signed Maine Rx rebate agreement with the Department. These drugs must be dispensed pursuant to a prescription although the medication may be available without a prescription.

B. Drug Rebate Program

1. No payment will be made for drugs of manufacturers or labelers that do not enter into a rebate agreement with the Department for drugs approved under the Program. The Department shall have drug rebate agreements with individual pharmaceutical manufacturers or labelers in amounts negotiated and agreed as between the Department and the manufacturer or labeler.

Each such agreement shall provide that the pharmaceutical manufacturer or labeler shall make quarterly rebate payments to the Department for the total number of dosage units of each form and strength of a prescription drug which the Department reports as reimbursed to providers of prescription drugs, provided such payments shall not be due until thirty (30) days following the manufacturer's receipt of utilization data from the Department including the number of dosage units reimbursed to pharmacies for prescription drugs during the period for which payment is due.

2. Upon receipt of such data from the Department, the pharmaceutical manufacturer or labeler shall calculate the quarterly payment. The Department may, at its expense, hire a mutually agreed upon independent auditor to verify the calculation and payment

In the event that a discrepancy is discovered between the pharmaceutical manufacturer's or labeler's calculation and the independent auditor's calculation, the pharmaceutical manufacturer or labeler shall justify its calculation or make payment to the Department for any additional amount due. The pharmaceutical manufacturer or labeler may, at its expense, hire a mutually agreed upon independent auditor to verify the accuracy of the utilization data provided by the Department.

In the event that a discrepancy is discovered, the Department shall justify its data or refund any excess payment to the pharmaceutical manufacturer or labeler.

3. Those prescription drugs of a pharmaceutical manufacturer or labeler that enters into an agreement pursuant to this subsection shall be immediately available and not subject to any restrictions or prior authorization requirements. Any prescription drug of a manufacturer or labeler that does not enter into such an agreement shall not be covered.

11. Dispensing of Drugs

Participating pharmacies are required to offer the consumer drugs from participating manufacturers when such products are available in the marketplace. A-rated generic drugs should be dispensed whenever possible.

12. Reimbursement

A. Claims must only be submitted to the Maine Rx Program if no other reimbursement option available. The Program provides access to discounted prescription drugs only when the individual does not have a comparable or superior prescription drug benefit plan.

B. The price charged to the eligible individual for all such prescription drugs will be a $3.35 dispensing fee plus the lowest of:

1. Federal Upper Limits (FUL) as defined in Chapter II, Section 80, Pharmacy Services, of the Medical Assistance Manual (MMAM);
2. Maine Maximum Allowable Cost (MMAC) as defined in Chapter II, Section 80, Pharmacy Services, of the MMAM;
3. Average Wholesale Price minus 6 percent (6%); or
4. Usual and Customary (U & C).

The Department assumes no liability for payments that are the responsibility of the consumer.

C. *Professional Fee*

For each prescription dispensed under this Program the pharmacist shall be reimbursed a $3.00 professional fee by the Department of Human Services.

D. The pharmacist shall clearly record on all claim forms for reimbursement for professional and dispensing fees under these rules all required information including patient name and identification number, date filled, drug name and drug type code, manufacturer, dosage form, strength, prescription number, estimated days supply, quantity, prescriber name and billing ID number and amount billed. The correct National Drug Code (NDC) must be used. Failure to use correct NDC code may result in a complete disallowance and/or recoupment for payments for incorrectly coded drugs.

E. *Claims Submission*

Participating pharmacies have the option to bill electronically or by paper claim.

1. *Electronic Format*. The electronic format shall be based on the same technical requirements as both the Maine Medicaid Point of Purchase (MEPOP) and Maine Low Cost Drugs for the Elderly and Disabled (DEL) prescription drug programs. This format shall comply with the National Council on Prescription Drug Programs (NCPDP) standards.

2. *Paper Claims*. No later than sixty (60) days after the date of service the completed forms shall be mailed to the Department's claim processing site. Failure to submit information in

a timely manner may result in nonpayment of claims.

13. Records for Audit Purposes

A. For each drug dispensed and for which a claim is submitted under the Program Agreement, the pharmacy shall maintain in permanent form an individual prescription, on the back of which shall be a record of each refill or, in compliance with State Pharmacy Law, a computerized record may be maintained. Said prescription shall be kept by the pharmacy either together with other prescriptions in a file of numerical or normally occurring order, or it may be maintained separately.

B. The pharmacy shall agree to submit to an audit, to be conducted by the Maine Department of Human Services or its designated agent, of records and transactions involving the dispensing of any and all prescription drugs under the Maine Rx Program. The pharmacy further agrees to furnish for review all materials and information regarding payment, including actual prescriptions, invoices for drug purchases, other appropriate documents, and any additional information which may be required by those authorized to determine compliance with this policy.

14. Fraud or Abuse

A. The State of Maine administers all of the funds for the Maine Rx Program and, therefore, pharmacies and participants are subject to Maine statutes pertaining to fraud.

B. Fraud also occurs when an eligible recipient allows, assists or conspires with an ineligible individual to obtain drugs under this Program.

C. All provisions relating to fraud and abuse and related sanctions outlined in Section I of the MMAM are applicable.

15. Prior Authorization

A drug manufacturer or labeler that sells prescription drugs in Maine through the Elderly Low-Cost Drug program (DEL) or any other publicly-supported pharmaceutical assistance program shall enter into a rebate agreement with the Department for this program. Drugs of non-participating drug manufacturers shall be reviewed by the Department as to the clinical appropriateness of prior authorization for those drugs under the Medicaid Program. Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Review Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and State law. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs.

16. Confidentiality

The Department shall protect the confidentiality of all information subject to confidentiality protection under State or federal law, rule or regulation.

Supreme Court, U.S.
FILED
SEP 20 2002
CLERK

No. 01-188

IN THE
Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

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September 20, 2002

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48 pp

QUESTIONS PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. § 1396 *et seq.*, precludes Maine from limiting Medicaid patients' access to prescription drugs as a means of compelling drug manufacturers to subsidize price discounts for non-Medicaid populations?

2. Whether Maine violates the Commerce Clause by requiring an out-of-state manufacturer that sells its products to wholesalers outside the state to remit a payment to the state each time one of the manufacturer's products is subsequently sold by a retailer within the state?

PARTIES TO THE PROCEEDING

Petitioner is the Pharmaceutical Research and Manufacturers of America ("PhRMA"). Respondents are Kevin Concannon, the Commissioner of the Department of Human Services of the State of Maine, and G. Steven Rowe, the Attorney General of the State of Maine.

Petitioner PhRMA is a not-for-profit incorporated membership organization. There are no parent corporations or publicly held companies that own 10% or more of PhRMA's stock. A list of PhRMA's members is found at http://www.phrma.org/whoweare/members/memlist.phtml?mbrType=members#membersListStart.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-53) is reported at 249 F.3d 66 (1st Cir. 2001). The opinion of the district court (Pet. App. 57-72) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 16, 2001. On June 13, 2001 the court of appeals entered an order denying rehearing and declining action on PhRMA's timely petition for rehearing *en banc* for lack of a quorum of judges able to act on the petition. PhRMA filed its petition for a writ of certiorari in this Court on July 31, 2001. The Court issued an order granting the petition on June 28, 2002.

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. Article I, Section 8, Clause 3 of the Constitution provides, in pertinent part, that "The Congress shall have Power ... To regulate Commerce ... among the several States."

2. Article VI, Section 2 of the Constitution provides, in pertinent part, that "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof ... shall be the supreme Law of the Land."

3. Title XIX of the Social Security Act governing the Medicaid Program, with particular reference to Section 1927 of the Act, 42 U.S.C. § 1396r-8, is reproduced in pertinent part at Pet. App. 73-84 and JA 253-60.

4. The Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) ("Maine Rx") is reproduced at Pet. App. 85-108.

STATEMENT OF THE CASE

This lawsuit challenges a Maine statute that restricts Medicaid patients' access to a manufacturer's drugs within the Medicaid program unless the manufacturer pays for price subsidies for non-Medicaid Maine consumers. If such payments are not made, Maine will subject the manufacturer's drugs to a "prior authorization" requirement, resulting in reduced access to those drugs for Medicaid beneficiaries and sharp reductions in the manufacturer's sales. The "Maine Rx" program thus leverages regulatory powers that Congress gave Maine to operate the Medicaid program to obtain funds from manufacturers to pay for a non-Medicaid program. This is flatly inconsistent with the Medicaid statute's mandate that Medicaid state plans be operated "consistent with ... the best interests of recipients." 42 U.S.C. § 1396a(a)(19). Holding Medicaid patients hostage to Maine's effort to reduce the costs of prescription drugs paid by other Maine residents interferes with the achievement of Congress's objectives in Medicaid and does so without any corresponding benefit to that federal program. It is therefore preempted under the Supremacy Clause.

This lawsuit also challenges Maine's demand for payments from manufacturers under the Commerce Clause. Out-of-state manufacturers whose only sales leading to the pharmacy counter take place outside Maine cannot be required to pay "rebates" to the state. Maine's demand regulates transactions occurring wholly outside Maine's borders, and confers a discriminatory subsidy on Maine consumers. Maine Rx thus violates the fundamental principle that a state may not achieve its social goals by regulating commerce in other states or shifting the costs of in-state benefits onto out-of-state interests.

I. THE MEDICAID PROGRAM

A. Congress created the Medicaid program in 1965 to provide medical care to eligible low-income individuals. The primary objective of the Medicaid program is:

> to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care.

Id. § 1396.

States that elect to participate in the Medicaid program receive federal funds to reimburse specified percentages of the states' expenditures on medical assistance. Each state must submit to the federal government for approval a plan setting out the medical assistance that it will provide. *Id.* § 1396a(a). Congress has specified certain categories of needy individuals who must be eligible for Medicaid benefits provided by a state; states have discretion to extend benefits to additional "medically needy" populations. *Id.* § 1396a(a)(10)(A), (C). The statute sets forth a number of requirements for state plans, including the requirement that they "provide such safeguards as may be necessary to assure that ... care and services will be provided, in a manner consistent with simplicity of administration and the best interests of recipients." *Id.* § 1396a(a)(19).

Under section 1927 of the Social Security Act ("SSA"), *id.* § 1396r-8, states may choose to provide a Medicaid prescription drug benefit and pay for drugs prescribed to Medicaid beneficiaries. As a condition of coverage of their drugs nationwide in the Medicaid program, drug manufacturers must agree to pay a "rebate" to each state on drugs used in treating Medicaid beneficiaries and paid for by the state. *Id.* § 1396r-8(a), (b)(1)(A). Manufacturers enter

into a national agreement with the Secretary of the Department of Health and Human Services ("HHS") to provide those rebates. Notice, 56 Fed. Reg. 7049 (Feb. 21, 1991).[1]

The Medicaid statute permits the states to impose certain access limitations on prescription drugs covered under their state plans. For example, states may maintain formularies, or lists of drugs that are preferred and covered by Medicaid without further restrictions, as long as, *inter alia*, any exclusions from those lists are based on written clinical assessments of the drugs. 42 U.S.C. § 1396r-8(d)(4). States may also subject covered drugs to "prior authorization," *id.* § 1396r-8(d)(1)(A). If a drug is subject to a prior authorization requirement, it will be paid for by Medicaid only if the prescribing physician first obtains patient-specific approval from state Medicaid authorities or their designated agents. The prior authorization system must at a minimum include specified procedural safeguards—namely, that prior authorization requests will receive a response within 24 hours, and that in emergency situations 72-hour supplies of drugs will be provided while requests are pending. *Id.* § 1396r-8(d)(5).

B. Prior authorization is used in the Medicaid program in conjunction with other limitations on prescription drug access spelled out in the statute. Such uses for prior authorization include policing quantity and refill limits for waste, fraud and abuse purposes, *id.* § 1396r-8(d)(6), and monitoring for

[1] The nationwide Medicaid rebate for a given drug is calculated based on data about the manufacturer's pricing around the country, using a formula set forth in the Medicaid statute. 42 U.S.C. § 1396r-8(c)(1). For brand-name (single source or innovator multiple source) drugs, the rebate is the greater of either (i) 15.1% of the average manufacturer price, or (ii) the difference between the average manufacturer price and the manufacturer's "best price," defined as its lowest price to any private or public purchaser (with limited exceptions) anywhere in the United States. *Id* § 1396r-8(c)(1)(A)-(C).

inappropriate or contraindicated uses identified by Medicaid Drug Use Review committees, *id.* § 1396r-8(g). If a state creates a drug formulary, it must also employ a prior authorization program to allow beneficiary access to drugs not on the formulary. *Id.* § 1396r-8(d)(4)(D).

A state may impose Medicaid prior authorization requirements only pursuant to a state plan approved by HHS. *Id.* § 1396r-8(d)(1), (5). A state must amend its state plan, and submit the amendment to HHS for approval, "whenever necessary to reflect...[m]aterial changes in State law, organization, or policy, or in the State's operation of the Medicaid program." 42 C.F.R. § 430.12(c)(ii).

C. Although Congress allowed it for these Medicaid uses, prior authorization indisputably burdens Medicaid patients and physicians, as the district court found (Pet. App. 68). It limits—indeed is meant to limit—Medicaid patients' access to drug therapies that otherwise would be readily available, and deters physicians from prescribing their first-choice drugs when those drugs are subject to prior authorization (JA 102-05, 111-12). This is so because the pressures of modern medical care mean that physicians have incentives to avoid cumbersome and time-consuming prior authorization requests by forgoing prescribing first-choice drugs in favor of different drugs for which prior authorization is not required (JA 104-05).[2] The deterrent effect is magnified when the state requires the physician to make a substantial showing to obtain prior authorization, or indicates that drugs will not be authorized unless other drugs have already been tried and failed. See, *e.g.*, *Maine Medical Assistance Manual* ch. II

[2] According to a recent study, the mean duration of an office visit in 1998 was 18.3 minutes per patient. *See* David Mechanic et al., *Are Patients' Office Visits with Physicians Getting Shorter?*, 334 New Eng. J. Med. 198, 200 fig.1 (2001). If the physician must dedicate an additional 15 or 20 minutes to preparing a written request for prior authorization to be submitted to the state Medicaid authorities, he or she will be able to see one fewer Medicaid patient.

§ 80.07-3 (2002) (requiring written prior authorization request), *available at* ftp://ftp.state.me.us/pub/sos/cec/rcn/apa/10/144/ch101/c2s080.doc; State of Me. Dep't of Human Servs., Prior Authorization Form, Miscellaneous Drugs Subject to PA (requiring explanation of "why ... this medication [is] medically necessary" and "what other alternatives were tried first"), *available at* http://www.ghsinc.com/Japps/upload/Miscellaneous.doc (last visited Sept. 19, 2002).[3]

Prior authorization requirements also subject patients to delay, anxiety, and even adverse health outcomes (JA 105). Medicaid patients may well learn about prior authorization for the first time at the pharmacy counter, when they are told that Medicaid will not cover their drug without it. There is a serious risk that patients will not follow up and ask their physicians to seek prior authorization, and will instead go without the prescribed drug therapy. See Owens et al., Florida Ctr. for Medicaid Issues, *Florida Medicaid Prescribed Drug Program, Four Brand Prescription Limit Policy: Final Report – Phase I*, at L04-L05 (June 2001) (see Petitioner's Lodging filed Sept. 20, 2002).[4] This may cause delay and even a second trip to the pharmacy, even if the physician proves willing to run the prior authorization gauntlet (JA 105). The confusion and possible medical

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[3] *Cf. Maine Medical Assistance Manual Proposed Rules* ch. II § 80.07-3 (2001) (JA 288) (listing required information, subsequently revised to require submission of form request).

[4] This recent study of Florida's Medicaid program, which required prior authorization for any prescription over a four-drug-per-patient limit, illustrates the likely outcomes. Out of some 155,000 instances in which pharmacies rejected prescriptions lacking prior authorization, in about 60% of the cases the prescribing physician then declined to pursue prior authorization. Some portion of that figure may represent cases in which the physician switched the patient to second-choice drugs rather than attempt to navigate through the prior authorization process. But the study reports that in over 25% of those cases, *no drug was dispensed* to the patient at all. Owens et al., *supra*, at L04-L05.

consequences are serious. See, *e.g.*, Roberta Scruggs, *Medicaid Patients Feel Sting of New Drug Rules*, Portland Press Herald, Feb. 4, 2001 (reporting patient harm, including hospitalization, in wake of expanded prior authorization requirements in Maine) (see Petitioner's Lodging filed Sept. 20, 2002).

These effects on patients and physicians are mirrored by the consequences for the companies supplying drugs that are subject to prior authorization. Drug manufacturers' experience indicates that subjecting a drug to prior authorization results in drastic losses of market share and severely reduced sales (JA 57-58, 102-06, 111-14).

II. THE MAINE RX PROGRAM

A. Maine's Act to Establish Fairer Pricing for Prescription Drugs , 22 Me. Rev. Stat. Ann. § 2681 *et seq.* (the "Act") (Pet. App. 85-108), requires drug manufacturers who participate in the national Medicaid program to subsidize retail price discounts to Maine residents under a new state program called "Maine Rx." Unlike Medicaid, the Maine Rx program is open to all residents of the state without regard to income or medical need.[5]

The Act requires all drug manufacturers whose products are ultimately sold in Maine to beneficiaries of public pharmaceutical assistance programs to enter into "rebate agreement[s]" with the state, separate and apart from their national Medicaid rebate agreements, that obligate them to make payments to a segregated fund used to subsidize retail

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[5] The Maine Rx program is open to any "qualified resident," defined as "a resident of the State who has obtained from the department [of Human Services] a Maine Rx enrollment card." 22 Me. Rev. Stat. Ann. § 2681(2)(F), (5) (Pet. App. 87, 88). The Commissioner's proposed implementing regulations specify Maine residency as the sole criterion for eligibility for the program. *See Proposed Rules of the Department of Human Services* ch. 130 §§ 1.3-.5 (proposed Oct. 5, 2000) (not finalized) (JA 311-12).

price discounts for Maine Rx participants. *Id.* § 2681(3) (Pet. App. 87). Because manufacturers' drugs are sold nationwide (including in Maine) under Medicaid, manufacturers' participation in that federal program automatically subjects them to Maine's new rebate requirements.

Signing the Maine Rx rebate "agreement" is mandatory. The Act states that a manufacturer "shall enter into" the required agreement, *id.*, and, as discussed below, penalizes manufacturers that do not enter into such agreements by subjecting their drugs to prior authorization in the Medicaid program, *id.* § 2681(7) (Pet. App. 89-90).

Under the agreement, a manufacturer must make a "rebate" payment to the state for each unit of a drug that is sold by a Maine pharmacy to a participating Maine resident. *Id.* § 2681(3) (Pet. App. 87); Maine Rx Program Rebate Agreement (JA 169-79). Manufacturer payments are to be paid into a dedicated state fund, which Maine will use to reimburse local retail pharmacies for prescription drug discounts for participating Maine residents.

Maine residents will tender a "Maine Rx" card at the pharmacy, and will be charged a discounted price set by the state. The state will then use the funds obtained from manufacturers to reimburse pharmacies for those discounts, plus "professional fees" of at least $3 per prescription. 22 Me. Rev. Stat. Ann. § 2681(5), (6) (Pet. App. 88-89). Maine makes no net contribution to these subsidies; they are to be funded entirely by the payments extracted from manufacturers.

B. The Act enforces its requirement that manufacturers pay for these non-Medicaid Maine Rx subsidies by threatening them with, *inter alia*, sanctions under the federal Medicaid program if they do not. If a manufacturer refuses to pay Maine Rx rebates, its drugs will be subject to a prior authorization requirement in the Medicaid program in Maine.

Id. § 2681(7) (Pet. App. 89-90).[6] A drug subject to prior authorization will not be available to Medicaid beneficiaries unless a physician first obtains special permission from state Medicaid officials or their agents to prescribe it to a Medicaid patient. Thus, the Act uses a Medicaid process, affecting Medicaid patients, to extract payments to subsidize non-Medicaid drug purchases.

To obtain prior authorization in Maine's Medicaid program, a physician must contact the Medicaid Pharmacy Program Coordinator and make a request in writing for permission to prescribe a listed drug to her Medicaid patient. *Maine Medical Assistance Manual* ch. II, § 80.07-3. At a minimum, the request must include the physician's explanation of why the medication is necessary, and what other alternatives (if any) were tried first. State of Me. Dep't of Human Servs., Prior Authorization Form, Miscellaneous Drugs Subject to PA.[7] For Maine Rx purposes, Maine has been clear that "it

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[6] The Act also penalizes such manufacturers by publicizing their noncompliance with the Act, 22 Me. Rev. Stat. Ann. § 2681(7) (Pet. App. 89-90), and threatens them with prosecution under so-called "anti-profiteering" provisions that create private and public causes of action for civil penalties and treble damages against anyone who "[e]xtracts or demands an unconscionable price," or obtains an "unjust or unreasonable profit" in sales of prescription drugs, *id.* § 2697(2) (Pet. App. 98-99). PhRMA obtained (and Maine has not appealed from) preliminary injunctive relief against the latter with respect to sales made outside Maine.

[7] Maine's process requires additional documentation for prior authorization of specific categories of drugs, such as NSAIDs and Cox-2 inhibitors for arthritis treatment, weight loss drugs, and growth hormones. The 20 different forms are available online at http://www.ghsinc.com/Japps/servlet/NewPAPage (last visited Sept. 19, 2002). To obtain certain non-sedating allergy drugs, for example, the physician must either certify that the patient "[f]ailed on at least 2 less costly antihistamines" or attach documentation of actual adverse effects of other, sedating allergy drugs on the patient's school or work performance. State of Me. Dep't of Human Servs., Prior Authorization Form, Non Sedating Antihistamines, *available*

will not authorize payment for the first choice drug manufactured by a [Maine Rx] non-participant where there is another drug for the ailment manufactured by a participant" (Pet. App. 15).

Maine has neither sought nor received HHS approval to amend its state Medicaid plan to incorporate the Maine Rx prior authorization sanctions. *Cf.* 42 U.S.C. § 1396r-8(d)(1), (5); 42 C.F.R. § 430.12(c)(ii). Nor has Maine limited the prior authorization requirements to those that serve Medicaid or even medical purposes, such as controlling over-prescription or guarding against drug interactions. Rather, Maine Rx will subject drugs (and Medicaid patients and physicians) to prior authorization solely because doing so will have the effect of punishing non-complying manufacturers by reducing their sales. Manufacturers know and expect that physicians will avoid the prior authorization process, and that physicians may not succeed in obtaining prior authorization even if they seek it. Accordingly, manufacturers understand that a refusal to pay the non-Medicaid rebates that Maine demands will mean that their drugs will not be prescribed to Medicaid beneficiaries in many cases where they otherwise would be prescribed (JA 57-58, 102-06, 111-14).

C. The Act requires pharmaceutical manufacturers to make rebate payments even if they are complete strangers to the in-state pharmacy sales transaction, and even if the manufacturer never engaged in *any* sales transaction in Maine leading up to that retail purchase. It is undisputed that there are currently no drug manufacturers located in Maine, and that manufacturers make few (if any) sales directly to anyone in Maine, much less retail sales to consumers (JA 50-51, 56-57, 76-77, 87-88, 110-11). Typically, pharmaceutical manufacturers sell drugs to national and regional wholesalers (all but one of which are also outside Maine) in transactions that

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at http://www.ghsinc.com/Japps/upload/Non_Sedating_Antihistamines.doc (last visited Sept. 19, 2002).

take place in other states (*id.*). Thus, the Maine Rx "rebate" is extracted by the state not from the actual in-state seller, or from any party to an in-state transaction; it is obtained from the out-of-state manufacturer, who makes only the first sale—to an out-of-state wholesaler—of a drug that ultimately is dispensed in Maine.

The "rebate" required from a manufacturer is set by reference to a national price benchmark: the rebate paid by manufacturers nationwide in the Medicaid program. The Maine Commissioner of Human Services is instructed to use his "best efforts"—backed by the sanctions of the Act—to secure a rebate for each drug that is at least as large as the federal Medicaid rebate amount. 22 Me. Rev. Stat. Ann. § 2681(4)(B) (Pet. App. 88). Implementing the Act's mandate, Respondent Concannon presented manufacturers with a form Maine Rx Program Rebate Agreement that dictated payment of "the Medicaid Rebate amount" (JA 62, 65, 89, 92). In later stages, the Act directs that the Maine Rx rebate shall match or exceed the rebates or price discounts in an additional category of out-of-state sales—namely, manufacturers' sales to any part of the federal government. 22 Me. Rev. Stat. Ann. § 2681(4)(C) (Pet. App. 88).

III. PROCEEDINGS BELOW

A. On August 10, 2000, PhRMA filed its complaint for declaratory and injunctive relief in the United States District Court for the District of Maine, claiming that the rebate provisions of the Act violate the Supremacy and Commerce Clauses of the U.S. Constitution. On October 26, 2000, finding PhRMA's likelihood of success on the merits of these claims to be "overwhelming," the district court issued a preliminary injunction against the implementation of the Maine Rx rebate program (Pet. App. 72).

The district court held that Maine had exceeded the territorial limits of its regulatory authority under the Commerce Clause. The district court found that, by exacting

rebates from drug manufacturers who sell their drugs outside the state, the Maine Rx Program unavoidably—and unconstitutionally—regulates those out-of-state sales (Pet. App. 64-66).

The district court also ruled that Maine's use of its Medicaid prior authorization power to penalize manufacturers who do not subsidize discounts under the non-Medicaid Maine Rx program necessarily burdened Medicaid recipients and posed an obstacle to Congress's express purpose of delivering Medicaid benefits to participants in that program. Because of that conflict between Maine and federal law, the district court found that the use of prior authorization to enforce Maine Rx rebate collections is preempted (Pet. App. 67-70).

B. On May 16, 2001, a panel of the court of appeals for the First Circuit reversed and vacated portions of the preliminary injunction (Pet. App. 28). The court of appeals held that, because the triggering pharmacy sales of the drugs take place in Maine, the effects of Maine's rebate demands do not constitute "extraterritorial" or discriminatory regulation in violation of the Commerce Clause.

The court of appeals also held that Maine's use of the Medicaid "prior authorization" sanction to compel payment of subsidies for *non*-Medicaid patients under Maine Rx does not inexorably conflict with the Medicaid program. The court declined to find a conflict absent evidence that prior authorization absolutely denies medically necessary drugs to Medicaid patients (Pet. App. 16). The court also expressed the view that Maine Rx subsidies might benefit the Medicaid program indirectly by potentially keeping some Maine residents from needing Medicaid assistance at some future date (*id.* at 13).

PhRMA timely sought rehearing. The court of appeals determined that the court could not act on the petition for rehearing *en banc* because all but one of the active judges of

the court were recused. The one active judge of the First Circuit who was not recused—Chief Judge Toruella—voted to rehear the case *en banc* "based on the opinion of the District Court" (Pet. App. 55). The court subsequently entered a stay of its mandate pending certiorari, which PhRMA timely sought on July 31, 2001 (JA 31-32). As a result, the Maine Rx program remains subject to the preliminary injunction against its implementation.

This Court granted review on June 28, 2002.

SUMMARY OF THE ARGUMENT

The Maine Rx program violates both the Supremacy and Commerce Clauses of the Constitution. Accordingly, the judgment below should be reversed.

By definition and by design, the Maine Rx program restricts Medicaid patient access to prescription drugs. Requiring prior authorization makes it more difficult for Medicaid patients to obtain the restricted drugs and drastically reduces sales of those drugs. Medicaid patients (and the drug manufacturers who would supply them) can be ransomed from this restriction only if the manufacturers make payments to the state. Those payments do not benefit the Medicaid patients whose ready access to prescription drugs is put at risk. Instead, they benefit other residents of the state. But federal law does not permit Maine to threaten Congress's intended beneficiaries in order to benefit other Maine residents. The use of regulatory powers granted by Congress for use in Medicaid, to ends that do not serve and and even burden Medicaid patients and the Medicaid program, is preempted as an obstacle to the achievement of Congress's purposes in the federal Medicaid statute.

Not only does the Maine Rx statute use Medicaid powers for non-Medicaid purposes, it also regulates conduct occurring wholly outside the state. Maine Rx requires every drug manufacturer in the nationwide Medicaid program to

pay the state each time *someone else* sells its drug to a Maine resident. But drug manufacturers are located outside Maine, sell almost exclusively to wholesalers outside Maine, and do not participate in the retail Maine Rx sales that take place in Maine. By sending a bill to a manufacturer, Maine is necessarily regulating the only sale the manufacturer does make in the chain of transactions leading to Maine—the wholesale sale outside Maine. Moreover, Maine ties the payments it demands to the prices charged by manufacturers outside Maine, throughout the country, in the Medicaid program and in sales to the federal government. This has the effect of regulating the prices manufacturers charge outside Maine. The Commerce Clause, however, forbids states from regulating prices and transactions in other states, and from exporting the costs of in-state subsidies to out-of-state entities. The Maine Rx rebate is therefore unconstitutional under the Commerce Clause.

ARGUMENT

I. MAINE'S USE OF MEDICAID PRIOR AUTHORIZATION POWERS FOR NON-MEDICAID PURPOSES CONFLICTS WITH THE FEDERAL MEDICAID STATUTE.

The Maine Rx program constricts the flow of prescription drug benefits to Congress's intended beneficiaries of Medicaid. This restraint does not advance clinical interests, or promote the interests of Medicaid patients or the Medicaid program. The sole purpose and effect of Maine's program is to coerce manufacturers to provide the state with funds to subsidize the drug purchases of a non-Medicaid population—namely, all other residents of Maine.

In effect, Maine is holding Medicaid patients' prescription drug benefits hostage to the state's fundraising efforts on behalf of others outside the Medicaid program. Such leveraging necessarily conflicts with the Medicaid statute.

Maine may not use a regulatory power conferred by Congress for use in Medicaid to the disadvantage of the very patients Congress intended to assist, or to undermine a careful bargain struck by Congress in the Medicaid statute.

State laws that impose obstacles to the accomplishment and execution of the Congressional objectives of a federal statute—here, Medicaid—cannot stand. *Pacific Gas & Elec. Co.* v. *State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 204 (1983); see also *Gade* v. *National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992); *Felder* v. *Casey*, 487 U.S. 131, 138 (1988); *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). Maine Rx is just such a law. It is in actual conflict with the "structure and purpose of the statute as a whole," *Gade*, 505 U.S. at 98 (citing *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 51 (1987)) because it burdens Medicaid beneficiaries without serving any Medicaid purpose.

A. Prior Authorization Burdens Medicaid Prescription Drug Benefits.

It should be beyond dispute that, as the district court found (Pet. App. 68) and as the Solicitor General observed in his *amicus curiae* brief at the certiorari stage, Maine Rx's prior authorization requirement "burden[s] the ability of Medicaid recipients to receive covered drugs." U.S. Br. at 11.

Prior authorization is by definition a procedural obstacle to providing physicians' first-choice drugs to Medicaid beneficiaries. The prior authorization process interferes with the physician's free selection of medications to treat his or her Medicaid patient, forcing the physician to choose between a first-choice drug that requires prior authorization and a second-choice, possibly less effective, drug that does not. Prior authorization requirements either deter physicians from prescribing drugs that would otherwise be their first choice, or consume the physicians' precious time and resources if they do prescribe those drugs.

In other words, but for a prior authorization requirement, any drug of a manufacturer participating in the national Medicaid program would be readily accessible to Medicaid patients and physicians without delay, and paid for by Medicaid without reservation. Once a prior authorization requirement is in place, however, a listed drug is no longer routinely available—it is available to the Medicaid beneficiary only if the patient's physician undertakes the cumbersome process of seeking authorization from state Medicaid officials, and ultimately succeeds in that effort.

In addition, Maine Rx-triggered prior authorization burdens the Medicaid program. It consumes federally-funded Medicaid resources, including the time and resources of the Medicaid Drug Utilization Review Committee that lists drugs for prior authorization, see 42 U.S.C. § 1396r-8(g); *Maine Medical Assistance Manual Proposed Rules* ch. II § 80.05-3 (proposed Oct. 5, 2000) (not finalized) (JA 278); *Proposed Rules of the Department of Human Services* ch. 130 § 1.15 (proposed Oct. 5, 2000) (not finalized) (JA 320); and of the Medicaid officials who must review physicians' prior authorization requests, *Maine Medical Assistance Manual Proposed Rules* ch. II § 80.07-3.

Maine has suggested that some drugs from nonparticipating manufacturers might not be prior authorized if they have unique therapeutic properties, and that some prior authorization requests will be granted if the physician can make the case that the chosen drug is "medically necessary."[8] But these assertions are beside the point. It is indisputable that prior authorization under Maine Rx will restrict Medicaid

[8] Maine cited changes to the Maine Medicaid regulations that the Commissioner proposed (but did not finalize) for purposes of implementing the Maine Rx program's prior authorization sanction. *See Maine Medical Assistance Manual Proposed Rules* ch. II § 80.05-3 (JA 278); *Proposed Rules of the Department of Human Services* ch. 130 § 1.15 (JA 320).

beneficiaries' access to prescription drugs, it cannot otherwise achieve its coercive effect. If the failure to pay Maine Rx rebates will not trigger prior authorization of at least *some* drugs—indeed, a substantial number of drugs—that would otherwise be readily available in Medicaid, the threat of prior authorization would be useless to Maine as a tool to coerce rebate payments from manufacturers. Likewise, no matter how the program is implemented, and regardless of whether a given physician can ultimately establish to Maine's satisfaction that a particular prescription drug is medically necessary, the prior authorization process interferes with the physician's free selection of medications to treat his or her Medicaid patient. As the district court found, while "the parties disagree on the severity of the obstacle," prior authorization "*is* an obstacle" (Pet. App. 68 (emphasis added)). This interference with the physician's choice of treatments for Medicaid patients is inherent and inescapable in the structure of the program.

The burden that prior authorization necessarily inflicts on Medicaid patients, doctors, and drug company sales is sufficient on its face to make out PhRMA's preemption case. PhRMA need not prove that prior authorization ultimately results in actual harm to the health of Medicaid beneficiaries.

Nevertheless, prior authorization does have significant, real-life consequences for Medicaid patients, physicians, and pharmaceutical companies. Prior authorization consumes precious time and resources, and artificially deters physicians from prescribing drugs that would otherwise be their first choice. It also burdens Medicaid patients, who may be put through trial-and-error routines on second-choice drugs in order to prove that they need a drug subject to prior authorization. Those same Medicaid patients, who by definition lack the financial resources to opt out, can also find themselves at pharmacy counters without the drugs their doctors have told them they need, and without the means to navigate the prior authorization bureaucracy. Though the

prior authorization obstacle may be procedural, the health consequences if patients are denied, or abandon the quest for, therapeutic prescription drugs are very real. Were there clinical or otherwise federally sanctioned reasons to take such risks with Medicaid patients' health, these consequences could be tolerable. But Maine Rx prior authorization will inflict such risks arbitrarily, based solely on whether a drug manufacturer has submitted to subsidizing a non-Medicaid program.

B. Prior Authorization For Non-Medicaid, Maine Rx Reasons Conflicts With The Object And Purpose Of Medicaid.

Although prior authorization by definition restricts the provision of physicians' first-choice drugs to Medicaid patients, Congress nevertheless decided that for certain uses the burden was outweighed by the benefits to the Medicaid program. See H.R. Rep. No. 101-881, at 98 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2110. The federal Medicaid statute thus permits states to impose prior authorization requirements for prescription drugs paid for by Medicaid consistent with the statute, and subject to certain procedural safeguards. 42 U.S.C. § 1396r-8(d)(1), (5). It is used, for example, to prevent abuse or over-prescription of popular but expensive medications. See *id.* § 1396r-8(g). It is also used to ensure that Medicaid beneficiaries have access to prescription drugs that have been excluded from states' clinically-based formularies when the drug is medically necessary for the patient. *Id.* § 1396r-8(d)(4). Both uses benefit Medicaid patients and promote Medicaid's efficient operation, as required by the statute. *Id.* § 1396a(a)(19), (30).

Here, however, the purpose of burdening Medicaid patients' access to drugs is not to benefit the Medicaid program or Medicaid beneficiaries, but to coerce funding by drug manufacturers of an unrelated state program from which Medicaid patients derive no benefit. "[T]he question whether a certain state action is pre-empted by federal law is one of

congressional intent. The purpose of Congress is the ultimate touchstone." *Gade*, 505 U.S. at 96 (alteration in original) (internal quotation marks omitted). Congress did not intend to allow Medicaid to be impaired solely to promote a state's non-Medicaid objectives.

1. Maine Rx Conflicts With Congress's Purpose Of Assisting Medicaid Beneficiaries.

The federal statute states that the Medicaid program's object and purpose is "to furnish ... medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396. Its actual scope, however, is considerably more specific. Congress intended to provide medical assistance such as prescription drugs specifically to Medicaid beneficiaries—a class identified by federal law that does not extend to the entire citizenry of Maine. See *id.* §§ 1396, 1396a(a)(10)(A), (C), 1396d(a); cf. *Schweiker* v. *Hogan*, 457 U.S. 569, 590 (1982) (citing legislative history that Medicaid beneficiaries are "'the most needy in the country and it is appropriate for medical care costs to be met, first, for these people'").

It is not enough that Maine Rx and Medicaid both seek to facilitate access to medical assistance (here, prescription drugs). State legislation that serves the same general ends as a federal statute can nonetheless run afoul of it on preemption grounds, by interfering impermissibly with Congress's objectives and the means chosen to implement them. See, *e.g.*, *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 379-80 (2000). More important, Maine Rx and Medicaid do *not* serve the same objectives. Medicaid offers medical assistance to specified classes of needy beneficiaries, while Maine Rx offers retail discounts to all Maine residents (no matter how capable they are of paying non-rebated prices), and does so by burdening Medicaid beneficiaries and the Medicaid program.

The Medicaid statute specifies that the goal of providing medical assistance must be implemented by the states in certain ways. See generally 42 U.S.C. § 1396a (listing requirements for state Medicaid plans). Of particular importance, § 1396a(a)(19) directs that state plans must "assure that ... care and services will be provided[] in a manner consistent with simplicity of administration and the best interests of recipients." Using Medicaid prior authorization for the benefit of non-Medicaid populations clearly violates this requirement. Congress's overarching objective is to provide medical assistance to specified beneficiaries. But the burden of Maine Rx prior authorization will be imposed on those very Medicaid beneficiaries solely in order to further Maine's interest in raising funds for non-Medicaid state residents. That burden in no way furthers, or pays any heed whatsoever to, the "best interests" of Medicaid recipients.

And far from simplifying Medicaid administration, Maine Rx adds to the program's administrative burden. Drugs never before involved in the Medicaid program's prior authorization system (namely, the drugs of nonparticipating manufacturers) will have to be reviewed by the Medicaid Drug Utilization Review Committee. Medicaid officials and contractors will have to review and respond to more prior authorization requests, and they will be evaluating physicians' "medical necessity" arguments for unfamiliar drugs that are new to the prior authorization system.

2. Maine Rx Conflicts With The Balance Struck By Congress In The Medicaid Drug Rebate Program.

The Maine Rx program also conflicts with Congress's specific objectives and purposes in creating the Medicaid prescription drug rebate program.

Prior to 1990, many states that provided a prescription drug benefit to Medicaid patients did so only on a limited basis.

Congress grew concerned that states were cutting costs by restricting the range of drugs for which Medicaid would make payment, thereby depriving Medicaid beneficiaries of the full range of up-to-date FDA-approved drug therapies.[9] At the same time, there was concern that Medicaid prescription drug expenditures were growing and that state Medicaid programs might be paying too much for covered drugs. As a result, in section 4401 of the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90"), Pub. L. No. 101-508, 104 Stat. 1388, 1388-143 to 1388-159, Congress enacted SSA section 1927 (codified at 42 U.S.C. § 1396r-8). This legislation struck a deliberate bargain. Each drug manufacturer would agree to pay rebates on all of its drugs paid for under states' Medicaid prescription drug benefits, using a statutory rebate formula designed to lower Medicaid's payments to levels comparable to manufacturers' best terms nationwide. 42 U.S.C. § 1396r-8(a)(1), (c). In return, all of the manufacturer's drugs would be covered under Medicaid, ensuring that Medicaid beneficiaries would have access to the full panoply of prescription drug therapies. *Id.* § 1396r-8(a)(1).[10] In

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[9] *See, e.g., Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 before the Senate Subcomm. on Health for Families and the Uninsured of the Comm. on Finance*, 101st Cong. 17, 19, 118, 136-37, 225 (1990) (noting problems with formularies and prior authorization programs).

[10] This tradeoff was spelled out explicitly in the House budget committee report on the bill, which explained:

> The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription

addition, states would be prohibited from maintaining formularies (lists of drugs for which reimbursement was readily available) that excluded the drugs of participating manufacturers. *Id.* § 1396a(a)(54) (1990).[11]

When Congress in OBRA 90 thus eliminated states' authority to cut costs by restricting beneficiaries' drug coverage, it did permit them to continue to use "prior authorization." See *id.* § 1396r-8(d)(1)(A). At the time, about 25 states used prior authorization, covering an "extremely small number" of drugs for medical-related reasons. See *Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 before the Subcomm. on Health for Families and the Uninsured of the Senate Comm. on Finance*, 101st Cong. 225 (1990) (Special Committee on Aging staff materials) ("In general, prior approval programs are used by many states—for a very small percentage of Medicaid-covered prescription drugs—to assure that the prescriptions dispensed are medically necessary."). Congress understood that prior authorization would continue to be used to "safeguard against unnecessary utilization" and to "assure that [Medicaid] payments are consistent with efficiency, economy, and quality of care." H.R. Rep. No. 101-881, at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110; see also 42 U.S.C. § 1396a(a)(30)(A). Importantly, prior authorization was *not* to be used to undermine Congress's desire to ensure that Medicaid beneficiaries have access to the full range of prescription drugs:

> However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements—i.e. assuring access by Medical [sic] beneficiaries to prescription drugs where medically necessary.

H.R. Rep. No. 101-881, at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110.

Thus, Congress in OBRA 90 struck a careful balance, trading expanded Medicaid prescription drug coverage for patients (by requiring states to cover all drugs of participating manufacturers, and reining in state cost-cutting restrictions like formularies) for Medicaid rebate payments from manufacturers. See *id.*; *Medicare and Medicaid Budget Reconciliation: Hearings before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce*, 103d Cong. 453 (1993) (Rep. Waxman, describing genesis of Medicaid drug rebate program's "government-industry compact").

Here, Maine has unilaterally altered that balance. Demands for Maine Rx rebates are triggered by a manufacturer's very participation in the Medicaid program. 22 Me. Rev. Stat. Ann. § 2681(3) (Pet. App. 87). Previously, a manufacturer entered into a national Medicaid rebate agreement in order to ensure that its drugs would be included in the Medicaid program. Under Maine Rx, that calculus changes: if the manufacturer chooses to participate in the national Medicaid drug program, it must pay rebates for drugs prescribed to Medicaid beneficiaries *and* rebates for drugs prescribed to Maine residents who are not Medicaid beneficiaries. Conversely, a manufacturer cannot avoid the reach of the Maine Rx program unless it pulls out of the national Medicaid program altogether. This diversion of the Medicaid program to serve non-Medicaid purposes strikes a new balance—one that Congress neither contemplated nor authorized. The

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> drugs to cover all of the products of any manufacturer that agrees to provide price rebates.

H.R. Rep. No. 101-881, at 96-97, *reprinted in* 1990 U.S.C.C.A.N. at 2108-09.

[11] Congress in 1993 restored states' ability to use formularies, but only under tightly controlled conditions. *See* 42 U.S.C. §1396r-8(d)(4).

national Medicaid program faces significant risks if states can unilaterally alter Congress's terms of participation.[12]

3. Maine Rx's Use Of Medicaid Prior Authorization Serves No Medicaid Purpose.

As the Solicitor General has observed, because prior authorization imposes a burden on Congress's intended beneficiaries, its use can be justified only if it furthers at least *some* Medicaid purpose. U.S. Br. at 13. Maine has disputed that premise, suggesting that because 42 U.S.C. § 1396r-8(d)(1)(A) provides that "[a] State may subject to prior authorization any covered outpatient drug," there is no limit of any kind to the uses to which prior authorization may be put. This is an obvious distortion of Congress's purpose for "prior authorization."

To be sure, the Medicaid statute does not expressly bar states from co-opting Medicaid prior authorization authority for non-Medicaid purposes. But the lack of an express prohibition on using Medicaid powers for non-Medicaid purposes is no license to do so. Congress may have stated that a state can impose prior authorization on covered drugs. See *id.* § 1396r-8(d)(1)(A). But Congress did not say that states can do so for "any reason." The limits on the states' authority are inherent in the structure, object and purpose of the statute.

As the district court recognized, the logical reach of a contrary rule—that Medicaid prior authorization can be put to *any* purpose—is untenable. "If Maine can use its authority

[12] 42 U.S.C. § 1396a(a)(30)(A) expresses an analogous concern, when it directs that states must ensure that payments to Medicaid providers "are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population." This provision recognizes that providers' financial incentives (like those of drug manufacturers) must be taken into account in order to assure adequate medical care for Medicaid beneficiaries.

over Medicaid authorization to leverage [rebates for Maine Rx], then it can just as easily put the rebates into a state program for highway and bridge construction or school funding" (Pet. App. 68). Congress cannot be deemed to have allowed the tools it provided for the operation of the Medicaid program and for the benefit of Medicaid recipients to be used for any other purpose that a state may imagine.

Although Maine cannot plausibly claim that Maine Rx prior authorization is in Medicaid patients' "best interests," Maine has adopted a post-hoc litigating position that Maine Rx may indirectly serve a Medicaid purpose, by perhaps reducing impoverishment of some non-Medicaid Maine residents, thereby potentially keeping them off Medicaid rolls. The court of appeals embraced this rationale, but it fails on two counts.

First, the Medicaid statute itself offers a mechanism for addressing Maine's newfound concerns about persons near to the Medicaid eligibility threshold: the state may seek HHS permission for a Medicaid "demonstration project" to aid those individuals, assuming it can establish to HHS's satisfaction, *inter alia*, that doing so promotes Medicaid objectives. 42 U.S.C. § 1315(a). The Maine Rx program, which is open to all Maine residents rich or poor, is not, and could not pass muster as, a demonstration project. And nowhere in the Maine Rx statute's statement of objectives is there any mention of concern for the fiscal integrity of the Medicaid program, much less any concern for the best interests of Medicaid beneficiaries. 22 Me. Rev. Stat. Ann. § 2681(1) (Pet. App. 86).

Second, if Maine's asserted Medicaid purpose were sufficient, the same reasoning would permit Maine to compel drug manufacturers to subsidize food stamps, public housing, job training programs, and any number of other public projects that would boost Maine residents' income and thereby potentially keep them off Medicaid. Congress did not intend to invite such broad misuse of the Medicaid program.

At the end of the day, the Solicitor General is correct in observing that "no Medicaid purpose appears to be served" by the Maine Rx program. U.S. Br. at 13. Without a Medicaid purpose, the Maine Rx use of prior authorization is necessarily inconsistent both with the "best interests" of Medicaid patients, 42 U.S.C. § 1396a(a)(19), and the Medicaid program. Maine Rx prior authorization is preempted, for the program cannot possibly be in the "best" interests of Medicaid patients if it serves *no* Medicaid purpose.

II. MAINE'S REBATE REQUIREMENT VIOLATES THE COMMERCE CLAUSE.

Maine had any number of constitutionally legitimate tools at its disposal for reducing drug costs to its citizens. It might have subsidized its citizens' drug purchases out of general revenues. It might have offered them state income tax credits for amounts spent on prescription drugs. And it might even have raised funds for the Maine Rx program by imposing a sales or excise tax directly on all retail pharmacy sales taking place in Maine.

But Maine did none of these things, choosing instead to take all the benefits of Maine Rx for its own citizens while imposing all the costs of its subsidy program on manufacturers residing and transacting virtually entirely out-of-state. This choice violates the Commerce Clause in either or both of two respects.

First, the Commerce Clause, by conferring power to regulate interstate commerce upon Congress, implicitly precludes any state from regulating transactions that take place outside its own borders. In particular, one of the negative implications of the Commerce Clause is that a state "has no power to project its legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there." *Baldwin* v. *G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935). The Maine Rx program runs afoul of this well-

settled extraterritoriality principle by regulating wholesale sales by manufacturers that take place wholly outside of Maine, and by using out-of-state prices as a benchmark for setting in-state rebates.

Second, even if Maine Rx were somehow viewed as regulating activity within Maine's borders, rather than wholesale transactions outside of them, it nonetheless violates the Commerce Clause because it seeks to impose virtually all of the costs of the program on manufacturers located outside Maine while directing all benefit from the program to its own citizens. This Court has struck down similar state attempts to evade the basic antidiscrimination principle of the Commerce Clause by linking an apparently nondiscriminatory levy to a local subsidy. As recently as in *West Lynn Creamery, Inc.* v. *Healy*, 512 U.S. 186, 188 (1994), for example, this Court invalidated as impermissibly discriminatory a Massachusetts milk assessment scheme that charged a premium on all sales of milk to Massachusetts retailers, but rebated all proceeds from this assessment through a special fund to Massachusetts dairy farmers.

A. The Maine Rx Rebate Requirement Constitutes Impermissible Extraterritorial Regulation.

Among the clearest implications of the Commerce Clause is that no state may regulate commerce in another state. In particular, as this Court has confirmed repeatedly, a state may not dictate the terms on which buyers and sellers do business outside the state. See, *e.g.*, *Brown-Forman Distillers Corp.* v. *New York State Liquor Auth.*, 476 U.S. 573, 583-84 (1986); *Healy* v. *Beer Inst., Inc.*, 491 U.S. 324, 338 (1989). Three factors help identify a state statute with an unconstitutional extraterritorial reach or effect that will render it virtually *per se* invalid: (i) whether the regulation is applied to commerce "'wholly outside of the State's borders,'" (ii) whether "the practical effect" of the regulation is to control such commerce, and (iii) what effect the regulation has on other states' regulations, as well as what effect would result "if not

one, but many or every, State adopted similar legislation." *Healy*, 491 U.S. at 336.

Thus, the Commerce Clause prohibits *de facto* extraterritorial state regulation even if the regulation is nominally predicated upon conduct that occurs within the state. That is exactly the case here, where Maine purports to be regulating in-state retail sales of prescription drugs, but in reality is regulating entities far removed (both geographically and commercially) from those pharmacy counter transactions. The critical inquiry—which Maine Rx fails—is whether "the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Id.* Whether the Maine Rx program is characterized as regulating the terms of out-of-state transactions, or as impermissibly tying in-state to out-of-state prices, its practical effect is clearly extraterritorial in violation of the Commerce Clause.

1. Maine Rx Rebates Regulate Wholly Out-Of-State Transactions.

The fundamental holding of *Baldwin*, *Brown-Forman*, and *Healy* is that states may not reach outside their borders to regulate the terms of transactions in other states. Here, Maine mandates payments from manufacturers whose only transactions leading to the pharmacy counter are with wholesalers. To the extent that those sales occur outside Maine—and virtually all manufacturers' sales do—Maine cannot mandate the Maine Rx payments consistent with the Commerce Clause. The only link to the state is that the goods flow through a stream of interstate commerce that the manufacturers do not control and ultimately come to rest on a pharmacy counter in Maine.

States may not regulate the price or terms on which goods are sold outside the state simply because the goods are later re-sold within the state. Rather, courts have limited the reach of a state's powers to transactions that actually take place within the state. See *Baldwin*, 294 U.S. at 528; *Dean Foods Co.* v. *Brancel*, 187 F.3d 609, 614-15 (7th Cir. 1999); *Louisiana Dairy Stabilization Bd.* v. *Dairy Fresh Corp.*, 631 F.2d 67, 69-70 (5th Cir. Unit A 1980), *aff'd*, 454 U.S. 884 (1981); *Schwegmann Bros. Giant Super Mkts.* v. *Louisiana Milk Comm'n*, 365 F. Supp. 1144, 1156 (M.D. La. 1973), *aff'd*, 416 U.S. 922 (1974) (mem.).

Virtually all manufacturers' sales of prescription drugs occur outside of Maine in transactions with wholesalers and distributors (JA 50-51, 56-57, 76-77, 87-88, 110-11). Typically, both the manufacturers and their customers (independent wholesalers and distributors) are located outside Maine. The drugs are usually delivered at the manufacturers' facilities outside Maine, and title and risk of loss pass outside Maine. The drugs are then shipped by common carrier to warehouses and distribution centers outside Maine. The wholesalers and distributors then sell the drugs to their customers, including pharmacies in Maine. Nevertheless, Maine Rx will exact a payment from a drug's manufacturer every time the drug crosses the pharmacy counter in Maine, even though the out-of-state manufacturer sold that product outside Maine to a wholesaler in another state and had no further role in the transactions that took the drugs to Maine.

The Maine Rx rebate has an effect similar to that of a duty imposed at the state's border: it reduces the effective price received by the manufacturer outside Maine on the units of its drugs that are eventually sold in Maine. That levy necessarily changes the economic terms of the only sales transactions in which manufacturers *are* engaged—namely, sales outside the state—by effectively reducing the revenues the manufacturers receive for their products from their wholesale customers. The manufacturer who is assessed the rebate will receive less net revenue on each wholesale transaction involving drugs that find their way to Maine (a result the manufacturer does not control and cannot predict). As the district court recognized, "whatever price the manufacturer originally

received for that out-of-state transaction is automatically reduced when the drug comes to Maine" (Pet. App. 66).

The First Circuit erroneously treated the Maine Rx rebate requirement as a regulation of the retail pharmacy sale of drugs, which does occur in Maine (Pet. App. 24). Maine has similarly suggested that Maine Rx rebates regulate the in-state retail sales, and have merely "incidental" effects on out-of-state manufacturers and their out-of-state wholesale transactions. Opp. Cert. at 20-21. Such a reading flies in the face of the statute. Other aspects of the Act, such as the provisions governing the prices to be charged by pharmacies to Maine Rx participants, 22 Me. Rev. Stat. Ann. § 2681(5) (Pet. App. 88-89), undoubtedly do regulate the pharmacy sales in Maine. But the exaction of "rebates" from manufacturers has no effect on, and is not directed to any party to, those in-state retail sales. The ultimate retail sales of the manufacturers' products merely generate the data that the state uses to calculate the dollar amount demanded directly, not "incidentally," from the manufacturers. When that demand is directed to out-of-state manufacturers based on their out-of-state sales, it violates the territorial limits of Maine's legislative authority under the Commerce Clause. The "practical effect" of the Act is to regulate the manufacturer's commerce occurring "wholly outside of the state's borders." *Healy*, 491 U.S. at 336.

If Maine's position were to prevail, then the state could well send a bill to any manufacturer of any product located anywhere in the country any time that manufacturer's product is sold—not by the manufacturer, but by others—in Maine. If the Maine legislature decides that the price of heating oil is too high, it might demand "rebates" from refineries in Texas whose output is sold to distributors who ship it to Maine. If the state chooses to promote computer literacy, it might demand "rebates" from California semiconductor manufacturers whose chips end up in computers sold in

Maine. Such schemes would obviously transgress the boundaries established by the Commerce Clause.

These boundaries are further illustrated by analogy to this Court's cases reading the Commerce Clause to limit the territorial reach of a state's taxation power. Because Maine Rx compels a payment to the state in connection with each sale of prescription drugs in Maine pharmacies to a Maine Rx cardholder, it resembles a sales tax. Were the Maine Rx rebate requirement to be assessed by the standards of this Court's interstate sales tax cases, however, it could not stand. See, *e.g.*, *Quill Corp.* v. *North Dakota ex rel Heitkamp*, 504 U.S. 298, 311, 315 (1992) (vendor whose only connection with customers in the taxing state is by mail or common carrier lacks substantial nexus required by Commerce Clause to impose sales tax liability) (citing *National Bellas Hess, Inc.* v. *Department of Revenue*, 386 U.S. 753 (1967) (overruled in part on other grounds)), *McLeod* v. *J.E. Dilworth Co.*, 322 U.S. 327, 330 (1944) (rejecting Arkansas efforts to impose sales tax liability on out-of-state vendor whose products were delivered into the state via common carrier); cf. *American Oil Co.* v. *P.G. Neill*, 380 U.S. 451, 457 (1965) (noting that the Court has "[m]ore than once ... struck down taxes directly imposed on or resulting from out-of-state sales which were held to be insufficiently related to activities within the taxing state, despite the fact that the vendor knew that the goods were destined for use in that State").

The basic framework of *Complete Auto Transit, Inc.* v. *Brady*, 430 U.S. 274 (1977), and its companion cases establishes that Maine may not tax out-of-state transactions unrelated to the state, nor impose sales tax liability on an out-of-state manufacturer merely because its products are sold in Maine by an unrelated third party. Under *Complete Auto*, only taxes that "[1] [are] applied to an activity with a substantial nexus with the taxing State, [2] [are] fairly apportioned, [3] do[] not discriminate against interstate commerce, and [4] [are] fairly related to the services provided

by the State" will survive Commerce Clause scrutiny. *Id.* at 279.

At a minimum, the Maine Rx program would fail the first of the *Complete Auto* elements. The Maine Rx rebate "taxes" drug manufacturers when third parties sell the manufacturers' products in Maine. While Maine clearly has the authority to tax in-state retail pharmaceutical sales, and may tax either the individual purchasers or the Maine-based pharmacies that sell drugs manufactured by PhRMA's members, it may not require out-of-state manufacturers who are strangers to the in-state retail transactions to bear the costs of this activity. Thus, if Maine purports to tax the only "activity with a substantial nexus to the taxing state" (*i.e.*, the retail sales), it may not impose this liability on out-of-state entities that are not involved in or responsible for that in-state activity.

Alternatively, if Maine purports to be taxing the "activity" of manufacturers—namely, wholesale sales—the Maine Rx rebate requirement even more obviously fails *Complete Auto*'s nexus requirement. Maine may not require out-of-state manufacturers to pay sales taxes on out-of-state wholesale transactions that have no relationship to the state of Maine. As noted *supra* at 29, virtually all of PhRMA members' product sales occur outside of Maine, in arms-length transactions with wholesalers and distributors, in which title and the risk of loss pass outside of the state. The activity in which the manufacturers are engaged thus has no nexus, much less a substantial one, to Maine.

2. Maine Rx Rebates Are Impermissibly Tied To Out-Of-State Prices.

The Maine Rx rebates separately violate the Commerce Clause because they impermissibly use out-of-state prices as a benchmark. The Act specifies that the "rebate required from ... manufacturer[s]" is to equal or exceed the rebates required around the country under Medicaid and other federal programs. 22 Me. Rev. Stat. Ann. § 2681(3), (4) (Pet. App.

87-88). Thus, the rebates that manufacturers must pay to Maine are tied to the rebates that manufacturers pay and prices they charge around the country.

This use of an out-of-state price benchmark for Maine's in-state mandatory rebate offends the principle set forth in *Brown-Forman* and *Healy*. In *Brown-Forman*, the Court struck down a New York law preventing distillers from varying their prices in a given month, and requiring an affirmation that the price in a each month was the lowest price at which the distiller would sell anywhere else in the United States. 476 U.S. at 575-76, 583-84. In *Healy*, the offending Connecticut law required beer distributors to certify that their in-state prices did not exceed prices charged in neighboring states. 491 U.S. at 328-29. In both cases, the law nominally regulated in-state activity, but had the effect of regulating prices outside the state.

The key offensive element of the price affirmation statutes in *Brown-Forman* and *Healy* was their effect on consumers and the competitive market in other states. The sellers in New York and Connecticut were prevented from setting prices in other states based solely on the competitive conditions prevailing there. If they lowered their prices in other states, they would have to change their New York and Connecticut prices as well; the in-state affirmation statutes altered their out-of-state pricing calculations.

As the Court explained in *Brown-Forman*, such state statutes, like the one here, are a form of protectionism toward in-state consumers: New York and Connecticut were advantaging their own consumers by depriving purchasers in other states of the benefits of local marketplace conditions. "While a State may seek lower prices for its consumers, it may not insist that producers or consumers in other States surrender whatever competitive advantages they may possess." 476 U.S. at 580; see also *Healy*, 491 U.S. at 339 (holding the Commerce Clause violated as the statute "requires out-of-state shippers to forgo the implementation of

competitive-pricing schemes in out-of-state markets because those pricing decisions are imported by statute into the Connecticut market regardless of local competitive conditions"). The Court thus condemned the price-tying on a *per se* basis—*i.e.*, as a direct regulation of out-of-state commerce—because it interfered with market-based competition in the out-of-state markets. See *Brown-Forman*, 476 U.S. at 580; *Healy*, 491 U.S. at 332.

Maine Rx's price tying operates in a similar way. By linking Maine Rx rebate levels to the federal Medicaid rebate level and to the lowest prices charged to the federal government, 22 Me. Rev. Stat. Ann. § 2681(3), (4) (Pet. App. 87-88), Maine is intruding into drug manufacturers' pricing decisions elsewhere in the nation. These two federal benchmarks give rise to the same kind of market pricing dynamics and extraterritorial effects that the Court condemned in *Healy* and *Brown-Forman*. The effect of the federal price benchmark, *id.* § 2681(4)(C) (Pet. App. 88), is straightforward. A manufacturer cannot charge a lower price to the federal government based *solely* on market conditions, because it also has to take into account the fact that the lower federal price will directly trigger a larger Maine Rx rebate.

The effect of the Medicaid benchmark, *id.* § 2681(4)(B) (Pet. App. 88), is the same, although slightly more complex in its operation. The Medicaid rebate amount for each brand-name drug is a function of the manufacturer's pricing decisions around the country. The statute bases the rebate on a manufacturer's national average price and the manufacturer's "best price" to a customer anywhere in the country. 42 U.S.C. § 1396r-8(c)(1). A drug manufacturer cannot lower prices charged to customers in California or Texas without taking into account the impact of those changes on the rebate it will owe to Maine. Previously, a new, lower "best price" would change only the rebates owed in the Medicaid program, a federal program in which the interests of the residents of all states are represented. Now, however,

Maine has unilaterally "project[ed] its legislation into [other states]," *Baldwin*, 294 U.S. at 521, because price changes in other states will change the rebates owed in Maine Rx as well.

Both Maine Rx benchmarks mean that a drug manufacturer can no longer set its out-of-state prices based solely on the out-of-state market conditions. Instead, when setting prices in out-of-state transactions, the drug manufacturer now must also factor the Maine rebate ramifications into its federal and nationwide pricing calculations. Even if that new factor may be a small one when it is only prescriptions for the 1.3 million residents of Maine at stake, there is no *de minimis* safe harbor for extraterritorial regulation under the Commerce Clause. Maine is no more entitled to regulate outside its borders than is California or Florida. Furthermore, if Maine's scheme is upheld, other states will surely follow Maine's lead and link in-state rebate demands to the federal Medicaid rebate level, drastically exacerbating the interference with "competitive pricing . . . based on prevailing market conditions," *Healy*, 491 U.S. at 338.

In sum, this Court's *Brown-Forman* and *Healy* precedents require the invalidation of the Maine Rx rebate program on the ground that it impermissibly fetters out-of-state price terms, interfering with interstate commerce.

B. The Maine Rx Rebate Requirement Impermissibly Discriminates Against Interstate Commerce In Order To Subsidize In-State Consumers.

Even if Maine Rx rebates were held not to operate extraterritorially, the Maine Rx program nonetheless violates the Commerce Clause because it externalizes the costs and internalizes the benefits of the program in a manner that, taken as a whole, is impermissibly discriminatory.

It is well-settled under the Commerce Clause that a state may not selectively exempt local economic actors from generally applicable burdens. See, *e.g.*, *Bacchus Imps. Ltd.* v. *Dias*, 468 U.S. 263, 265 (1984) (invalidating exemption from

Hawaii liquor tax for beverages produced only locally), *New Energy Co.* v. *Limbach*, 486 U.S. 269, 279-80 (1988) (invalidating a fuel tax credit solely for ethanol produced in-state). Furthermore, the Court explained in *West Lynn*, 512 U.S. at 188, that a state may not evade this antidiscrimination principle by using a two-step process of imposing a general burden, but using its proceeds to furnish a subsidy solely to in-state economic interests.

West Lynn invalidated a Massachusetts milk pricing order that levied an assessment on all retail sales of milk in Massachusetts (most of which was produced out of state), placed the proceeds in a segregated fund, and distributed that fund in turn to Massachusetts dairy farmers. The Court held this linked charge-and-subsidy scheme to be impermissibly discriminatory, even if a nondiscriminatory charge and a cash subsidy independently would each have been constitutional. The Court explained:

> Even granting respondent's assertion that both components of the pricing order would be constitutional standing alone, the pricing order nevertheless must fall. A pure subsidy funded out of general revenue ordinarily imposes no burden on interstate commerce, but merely assists local business. The pricing order in this case, however, is funded principally from taxes on the sale of milk produced in other States. By so funding the subsidy, respondent not only assists local farmers, but burdens interstate commerce.

Id. at 199 (footnotes omitted).

This case is analogous to *West Lynn* and should reach the same result under the Commerce Clause. Here, as in *West Lynn*, the state has imposed a requirement for payments whose incidence falls overwhelmingly on out-of-state manufacturers. Here, as in *West Lynn*, the state segregates all the proceeds of that assessment in a separate "dedicated" fund apart from its general treasury. See *id.* at 210-12 (Scalia, J., concurring in judgment) (emphasizing this distinction). And here, as in *West Lynn*, the state remits rebates from that fund solely to in-state economic interests—here, to in-state retail pharmacists and to in-state consumers. Thus, here, as in *West Lynn*, the state's decision to force out-of-state interests to bear the cost of a subsidy created for the state's own citizens should be invalidated.

Moreover, Maine Rx implicates the concerns stated long ago by Chief Justice Stone, who wrote that "the court has often recognized that to the extent ... the burden of state regulation falls on interests outside the state, it is unlikely to be alleviated by the operation of those political restraints normally exerted when interests within the state are affected." *Southern Pac. Co.* v. *Arizona ex rel. Sullivan*, 325 U.S. 761, 767 n.2 (1945). There is even less reason here than in *West Lynn* to expect in-state political processes to safeguard the interests of interstate commerce. As the Court noted there:

> when a nondiscriminatory tax is coupled with a subsidy to one of the groups hurt by the tax, a State's political processes can no longer be relied upon to prevent legislative abuse, because one of the in-state interests which would otherwise lobby against the tax has been mollified by the subsidy.

West Lynn, 512 U.S. at 200. In the Massachusetts case, "dairy farmers, milk dealers, and consumers" should all have lobbied against the milk premium, "[b]ut because the tax was coupled with a subsidy, one of the most powerful of these groups, Massachusetts dairy farmers, instead of exerting their influence against the tax, were in fact its primary supporters." *Id.* at 200-01. Here, no local forces exist to protect the interests of out-of-state manufacturers or out-of-state consumers in the political process. Maine consumers obviously benefit directly from the subsidy, while Maine retail pharmacists, who might otherwise be concerned about facing higher prices, are "mollified" by the state's transfer to

them of Maine Rx rebates and a $3 "professional fee" for each prescription.

To be sure, *West Lynn* differs from this case in one respect: there, Massachusetts sought to enable high-cost local milk producers to compete with lower-cost milk producers located outside the state, which the Court analogized to imposition of a tariff on out-of-state milk. See *id.* at 194-95. Here, there are no Maine pharmaceutical manufacturers to be similarly protected. But that feature was neither necessary nor dispositive in *West Lynn*. To the contrary, *West Lynn* expressly rejected Massachusetts' argument that its scheme was not discriminatory because the milk dealers who paid the tax did not compete with the dairy farmers who reaped the subsidy. The Court reasoned that what matters is the burden that discrimination places "on any part of the stream of commerce—from wholesaler to retailer to consumer[.] [A] burden placed at any point will result in a disadvantage to the out-of-state producer." *Id.* at 202.

In sum, the Maine Rx rebate scheme represents a new variation on state efforts to externalize the costs of local subsidies upon out-of-state economic interests. Accordingly, it is barred by the Commerce Clause.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be reversed.

Respectfully submitted,

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Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, Commissioner, Maine Department of Human Services, and G. STEVEN ROWE, Attorney General of Maine,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

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QUESTIONS PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. 1396 *et seq.*, prohibits a state from using its prior authorization powers under that statute to compel drug manufacturers to provide rebates for drugs sold to uninsured Maine residents?

2. Whether the Maine Rx statute, 22 Me.Rev.Stat. Ann. § 1281 *et seq.*, which seeks rebate payments in connection with in-state retail sales of prescription drugs to uninsured Maine residents, violates the dormant Commerce Clause because wholesale transactions in those drugs occur outside of Maine?

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CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

In addition to those set forth in Petitioner's brief, the following provision of the Constitution is involved in this matter:

> Article I, Section 8, Clause 1 of the Constitution provides, in pertinent part, that "The Congress shall have Power . . . to pay the debts and provide for the common Defence and general Welfare of the United States."

STATEMENT OF THE CASE

Maine Rx is an effort to preserve and protect the health of Maine residents by lowering the cost of medications to individuals who benefit from neither private insurance nor other public plans. Through this program, Maine seeks to use Medicaid's prior authorization process to encourage pharmaceutical manufacturers to provide rebates on medicines purchased by those individuals. The drugs of those manufacturers that do not agree would be subject to prior authorization in the Medicaid program to the extent permitted by law. Nothing in the language, structure or goals of the Medicaid statute forbids such use of prior authorization.

The Pharmaceutical Research and Manufacturers of America (PhRMA) makes a facial challenge to this statute, arguing that it is both preempted and in contravention of the Commerce Clause. Maine Rx does not burden Medicaid, and, to the extent relevant, does advance its objectives. Maine Rx, moreover, does not discriminate between

in-state and out-of-state competitors and does not regulate out-of-state transactions.

The Solicitor General agrees that Maine Rx does not violate the Commerce Clause, and generally agrees that the structure and purpose of Maine Rx does not contravene Medicaid. The government's primary objection is that Maine has sought to help too many uninsured residents, some of whom, in its view, are not sufficiently needy. The inclusion of this group in the program, however, has not been shown to burden Medicaid.

I. STATUTORY FRAMEWORK

A. Medicaid

1. Medicaid was created by Congress in 1965 pursuant to its spending power under Article I, section 8, clause 1 of the Constitution. The program is one of "cooperative federalism," whereby the federal government provides money to the States to assist them in providing "necessary medical services" to their most needy residents. 42 U.S.C. 1396.

In order to participate, a State must have its Medicaid "State plan" approved by the Centers for Medicare and Medicaid Services (CMS), on behalf of the Secretary of the Department of Health and Human Services (the Secretary), and, once approved, the State is eligible for federal reimbursement for portions of state expenditures on medical assistance under the State plan. 42 U.S.C. 1396a, 1396d(b). One of the forms of "medical assistance" that can be made available through Medicaid is prescription medication. 42 U.S.C. 1396d(a)(12). Drugs have become a major benefit provided by Medicaid. By 1988, for instance,

pharmaceuticals constituted the third largest category of medical assistance offered through Medicaid, eclipsing the amount spent to compensate physicians. *Medicaid Prescription Drug Pricing: Hearing on S.2605 and S.3029 Before the Subcomm. on Health for Families and the Uninsured of the Senate Comm. on Finance*, 101st Cong., 2d Sess. 2 (1990) ("*Medicaid Prescription Drug Pricing*") (statement of Sen. Riegle).

2. By 1990, the escalating cost of prescription drugs was seriously straining the resources of State Medicaid programs. See *Medicaid Prescription Drug Pricing, supra* at 3 (statement of Sen. Pryor) (noting a 152 percent increase in prescription drug prices over the previous decade and the resulting impact on State Medicaid programs). Manufacturers were charging Medicaid programs a much higher price for prescription drugs than they were charging their other large purchasers. H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990); see also *Medicaid Prescription Drug Pricing, supra* at 3. (statement of Sen. Pryor) ("In essence, the drug manufacturers are holding the States and the Federal Government hostage to their price increases.").

Realizing that traditional market forces had failed to ensure Medicaid programs the price concessions typically demanded by large customers, in 1990 Congress prohibited the States from using federal funds to purchase any prescription drugs unless the manufacturer paid an acceptable "rebate." 42 U.S.C. 1396r-8, *et seq.*, enacted as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), Pub. L. No. 101-508, § 4401, 104 Stat. 1388-143. This "rebate" provision generally requires that federal funds only be applied towards a net purchase price that is at least as low as the "best price for which a manufacturer

sells a prescription drug to any public or private purchaser." 42 U.S.C. 1396r-8(c); U.S. Br. 4-5. The Medicaid statute, as amended, sets the minimum rebate amount a state must receive before federal funds will be available. On behalf of all of the states, the Secretary negotiates agreements with manufacturers that provide this minimum rebate. Individual states may negotiate more generous agreements providing for rebate payments exceeding the minimum. 42 U.S.C. 1396r-8(a)(1).[1]

3. The use of "prior authorization" as a tool to save money and to negotiate rebates has always been the prerogative of the states under Medicaid. 136 Cong. Rec. 30, 515 (1990) (noting that States engage in prior authorization without federal or regulatory constraints and that they are free to negotiate discounts with manufacturers). Medicaid will cover the costs of any drug prescribed to a Medicaid beneficiary, provided that the manufacturer has agreed to pay a rebate. When a drug is subjected to prior authorization, however, the State Medicaid agency must approve a doctor's prescription of the drug in order for there to be Medicaid reimbursement. J.A. 288-291.

In 1990, at the same time that it conditioned the release of federal money on receipt by the States of at least the minimum rebate amount, Congress affirmed and ratified the States' broad and historic power to impose prior authorization. Thus, the 1990 amendment to Medicaid provides that "[a] State may subject to prior

[1] The agreement reached must be approved by the Secretary. 42 U.S.C. 1396r-8(a)(1).

authorization *any* covered outpatient drug."[2] 42 U.S.C. 1396r-8(d)(1)(A) (emphasis added). The States could impose prior authorization to achieve "efficiency, economy and quality of care." H.R. Rep. No. 881, 101st Cong., 2d Sess. 98 (1990); U.S. Br. at 14-15. Cost-saving is undeniably a goal in administering Medicaid, and prior authorization is a tool to achieve it.

Congress deemed it best that the State Medicaid agencies – as the governmental authorities most sensitive to the needs of Medicaid recipients and physicians who treat them – hold the power to impose prior authorization. Congress made that decision fully aware of allegations that prior authorization pushes doctors toward prescribing less effective medications. *Medicaid Prescription Drug Pricing, supra* at 7-8. The only significant limitation Congress placed on prior authorization was to address the concern that some states were not responding to physicians' prior authorization requests in a timely fashion. Congress thus required that states respond to prior authorization requests within 24 hours and that in emergencies they provide a 72-hour supply notwithstanding the lack of authorization. 42 U.S.C. 1396r-8(d)(5). Three years later Congress added the concept of a formulary (a list of favored drugs) as a fiscal tool, but was careful to leave prior authorization untouched. 42 U.S.C.

[2] Medicaid permits the States to impose a variety of limitations on access to drugs. 42 U.S.C. 1396r-8(d). PhRMA argues (Br. 4-5) that prior authorization is merely the means of achieving these other limitations. But the structure of the statute clearly establishes prior authorization as a separate and distinct power, limited only by the patient protection provisions of 42 U.S.C. 1396r-8(d)(5) and the overarching requirement that Medicaid patients receive all medically necessary prescription drugs. 42 U.S.C. 1396.

1396r-8(d)(4) ("[a] prior authorization program . . . is not a formulary. . . . ").

As the Solicitor General explains, following the grant of the petition for *certiorari* the Secretary confirmed that prior authorization can be used as a tool in negotiating with drug manufacturers to benefit *non*-Medicaid citizens. In a letter sent to the nation's State Medicaid Directors on September 18, 2002, the Secretary conveyed his understanding that Medicaid permits the threat of prior authorization to be used as leverage to negotiate not only for supplemental Medicaid rebates but also for discounts, rebates, and other prescription drug benefits for persons *not* eligible for Medicaid. U.S. Br. 48a-49a.

B. Maine Rx

1. There is no real dispute that people without Medicaid or private insurance covering pharmaceutical expenses pay much more to fill their prescriptions than any other purchasers. Department of Health and Human Services, *Report to the President, Prescription Drug Coverage, Spending, Utilization, and Prices,* April 2000, p. 96; table 3-1, p. 98, http://aspe.hhs.gov/health/reports/drug study/ ("*Report to the President*"). This price discrimination persists because, *inter alia,* there is no purchasing agent to negotiate on behalf of the uninsured. As prices for the uninsured continue to rise, many prescriptions for vital medicines go unfilled.[3]

[3] In 2000, an estimated 22.2% of all Maine residents lacked insurance for prescription drugs. Alan Sager, *Cutting Prescription Drug Spending By Paying Federal Supply Schedule Prices*, Boston University School of Health 1 (Aug. 2000). In 1996, the average Maine senior paid

(Continued on following page)

Maine Rx ameliorates this price discrimination by providing a price discount to the uninsured. Those with prescription drug coverage will not avail themselves of this benefit because the small co-payments typically required by their insurance plans are far less than the after-discount price available to Maine Rx beneficiaries. Thus, enrollment in the program will be self-limiting, as Maine's legislature intended. See 22 Me. Rev. Stat. Ann. § 2681(1) (Maine Rx is not intended to "discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans.") It would be economically irrational for a person with prescription drug coverage to use Maine Rx, but if any patient mistakenly attempts to do so, the Department of Human Services (DHS) has proposed regulations which will not allow it. J.A. 317.

cash for 48.1 percent of their prescription drug expenditures. Amanda McCloskey, *Cost Overdose: Growth in Drug Spending for the Elderly*, Families USA Foundation, 10 (July 2000). In 1998, the average retail price charged in Maine for the ten drugs most commonly used by the elderly was 86 percent higher than the price paid by the manufacturers' most favored customers. Minority Staff Report, *Prescription Drug Pricing in the 1st Congressional District of Maine: Drug Companies Profit at the Expense of Older Americans*, Committee on Government Reform and Oversight, U.S. House of Representatives, prepared for Rep. Thomas H. Allen, ii (Oct. 9, 1998) ("*Prescription Drug Pricing in the 1st Congressional District of Maine*"). Faced with the highest drug prices in the market, some uninsured must choose between buying food and medicine. Others skip doses, split pills or do not fill their prescriptions at all. *Id.* at 4, 16. See also Stephen B. Soumerai, et al., *Inadequate Prescription-Drug Coverage for Medicare Enrollees – A Call to Action*, 340 New Eng. J. Med. 723 (1999). The authorities cited above appear in the record accompanying Defendant's Memorandum of Law in Opposition to Plaintiff's Motion for Preliminary Injunction (Def. Opp. Mot. Prelim. Inj.).

Maine Rx achieves price discounts for the uninsured by empowering DHS to act as a pharmaceutical benefits manager (PBM) to negotiate for "manufacturer rebates and pharmacy discounts" on their behalf. 22 Me. Rev. Stat. Ann. § 2681; Pet. App. 86. The PBM model on which Maine Rx is patterned dominates the private sector health care system. Private PBMs are purchasing agents retained by employers, benefit plans, and insurers to negotiate discounts with manufacturers and pharmacies on their behalf. *Report to the President, supra* at 102-05; see also William H. von Oehsen, III, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*, Public Health Institute (2001) 5-6, available at http://www.phpc-rx.org/PHI.Pharm.pdf. PBMs can wield market power because they are able to influence which drugs are dispensed to the individuals participating in the benefits programs they manage. *Id*; see also Pet. App. 38.

Under Maine Rx DHS will induce manufacturers to participate in the program by wielding its purchasing power – specifically its power to subject to prior authorization requirements the drugs it covers through Medicaid. Maine Rx thus relies on the hope and expectation that manufacturers would rather negotiate discounts for the uninsured than find their drugs placed in a disadvantaged position relative to competing and therapeutically similar drugs produced by companies electing to participate in Maine Rx. 22 Me. Rev. Stat. Ann. § 2681(7); Pet. App. 89-90. As noted previously, the Secretary has specifically approved of this approach to benefit residents not eligible for Medicaid benefits.

2. The mechanics of the Maine Rx program are not complex. The Commissioner of DHS (Commissioner) will negotiate with pharmaceutical manufacturers to obtain discounts for qualified residents. The discounts take the

form of rebates triggered by each sale of a Maine Rx covered drug to a Maine Rx cardholder at a participating Maine Rx pharmacy. Maine Rx does not mandate any particular rebate amount – the Commissioner is simply to use his "best efforts" to leverage the State's market power into the most generous discount manufacturers are willing to provide. The initial *goal* is a rebate equal to or greater than the rebate Maine typically receives when it purchases drugs through its Medicaid program (discussed above), with an ultimate goal of rebates approximating those provided to the federal government. 22 Me. Rev. Stat. Ann. § 2681(4); Pet. App. 88. Once an agreement is negotiated, the discounts made possible by Maine Rx rebates will be deducted by participating pharmacies at the point of purchase. 22 Me. Rev. Stat. Ann. § 2681(5); Pet. App. 88. Participating manufacturers will pay rebates quarterly based upon the volume of their drugs purchased by Maine Rx enrollees. 22 Me. Rev. Stat. Ann. § 2681(3); Pet. App. 87.

Under the Maine Rx statute and the administrative rules drafted to guide DHS in implementing the program, prior authorization will consist of a three-step process. First, Maine's Drug Utilization Review Committee will be presented with a list of drugs manufactured by companies that have declined to participate in the Maine Rx program. J.A. 278, 320. Second, the committee, which is comprised of physicians and pharmacists, will consider, on a drug-by-drug basis, whether or not it is "clinically appropriate" to subject a drug on the list to prior authorization. J.A. 149, 268, 278, 320. For instance, a drug with a unique therapeutic use will not be subjected to prior authorization for that use because it would always be medically necessary. J.A. 149. Finally, for drugs which are subjected to prior

authorization, DHS will approve a request to dispense such a drug upon a showing by the treating physician that the patient needs that drug. J.A. 278, 288-91, 320. DHS employs pharmacists to participate in this process. J.A. 151. The proposed administrative rules reflect the statute's mandate that prior authorization be imposed on the drugs of non-participating manufacturers only "as permitted by law." 22 Me. Rev. Stat. Ann. § 2681(7); Pet. App. 89-90. This three-step prior authorization process fully comports with Maine's obligation under Medicaid to provide a "quality of care" that is "consistent with . . . the best interests of the recipients." 42 U.S.C. 1396a(a)(30) and (19).

II. PROCEEDINGS BELOW

One day prior to Maine Rx's effective date, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a complaint setting forth a facial constitutional challenge based on the Supremacy Clause and the Commerce Clause. On October 26, 2000, the United States District Court for the District of Maine granted PhRMA's motion for a preliminary injunction. The court construed the rebate mechanism as an impermissible price control in violation of the dormant Commerce Clause even though it does not discriminate against interstate commerce. Pet. App. 64-66. The court also held that Maine Rx is preempted by Medicaid because it uses Medicaid prior authorization without advancing the interests of either the Medicaid program or its current beneficiaries. Pet. App. 68.

On May 16, 2001, a unanimous panel of the Court of Appeals for the First Circuit reversed. After finding that PhRMA has prudential standing to raise a preemption

objection to Maine Rx, the court of appeals held that the statute survives the attack on the merits because it does not conflict with the purposes of Medicaid. Pet. App. 8, 13. The circuit court recognized that Maine need not shoulder the burden of demonstrating that Maine Rx affirmatively advances the aims of Medicaid. Pet. App. 13. Nonetheless, the court concluded that even if that were the test, Maine Rx would pass muster because it tends to preserve the fiscal viability of Medicaid by keeping the uninsured healthy and employed so that they will not slip further into poverty and, consequently, Medicaid eligibility. *Id.*

Turning to PhRMA's Commerce Clause challenge, the circuit court rejected the notion that seeking rebates from an out-of-state manufacturer violates the dormant Commerce Clause. The court held that while such a rebate might have an effect on manufacturers' profits, such an effect does not constitute impermissible regulation of out-of-state transactions. Pet. App. 23. Finally, after noting that PhRMA had not alleged that Maine Rx discriminates against interstate commerce, the court held that whatever incidental burden Maine Rx might actually have on interstate commerce was not "'clearly excessive' as compared" to the local health benefits for Maine's uninsured residents. Pet. App. 25-27 (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)).

PhRMA sought a panel rehearing and a rehearing *en banc*. The panel refused to rehear the case, and, because the full court was unable to consider the request for *en banc* review due to the recusal of all but one of the active judges of the court, that motion was also denied. Pet. App. 55-56. Thereafter, upon PhRMA's further motion, the court

granted a stay of its mandate pending *certiorari*. J.A. 31-33.

This Court granted *certiorari* review on June 28, 2002. Consequently, the order of the circuit court granting a stay of its mandate remains in force, as does the October 26, 2000 injunction issued by the district court.

SUMMARY OF THE ARGUMENT

Maine Rx is not preempted by Medicaid and does not violate the Commerce Clause. The judgment of the circuit court should be affirmed.

1. PhRMA fails the zone of interest test required for prudential standing. Federal law does not provide the requisite interest because Medicaid was not enacted to protect the interests of pharmaceutical manufacturers or to regulate that industry, and none of its provisions has that effect. Nor can the requisite interest be derived from the Supremacy Clause, which concerns the relative powers of the state and federal government in our constitutional system and does not, in and of itself, create interests.

2. Medicaid does not preempt the Maine Rx program. Medicaid expressly authorizes the States to impose prior authorization on *any* prescription drug, and Maine has satisfied the few conditions imposed on that authority. There is no implied preemption because Maine Rx does not irreconcilably conflict with the primary purposes of Medicaid. To the extent relevant, Maine Rx advances the goals of Medicaid by preserving the health and productivity of Maine residents who lack insurance. Maine Rx also creates financial benefits for Medicaid by using prior

authorization to reduce the State's purchase of unduly expensive drugs, by limiting the growth of the Medicaid rolls, and by increasing the State's power to negotiate lower prices for prescription drugs.

3. Maine Rx also does not infringe the dormant Commerce Clause. The Act does not discriminate against interstate commerce because it does not give in-state economic actors an advantage over out-of-state competitors. Maine Rx allows the interstate market to function without restraint and is wholly consistent with the principle of a national economic union. It has neither the purpose nor effect of protecting in-state industry. Further, Maine Rx is not an impermissible extraterritorial regulation. It has no effect on prices in other states, directly or indirectly. Regardless of whether Maine Rx rebates affect drug manufacturers' profits, the Act is not a price control and does not regulate out-of-state wholesale transactions. The Solicitor General agrees that Maine Rx does not run afoul of the dormant Commerce Clause. U.S. Pet. Br. at 15-18.

ARGUMENT

I. PhRMA DOES NOT HAVE PRUDENTIAL STANDING TO ASSERT THAT MAINE RX IS PREEMPTED BY MEDICAID.

The circuit court concluded that PhRMA's interests need not fall within the zone of interests protected or regulated by the Medicaid statute, instead finding that PhRMA has prudential standing "grounded in the Supremacy Clause" itself. Pet. App. 7-8. This was error.

Prudential standing is a "judicially self-imposed limit[] on the exercise of federal jurisdiction." *Allen v. Wright*, 468 U.S. 737, 751 (1984). Like the "irreducible constitutional minimum of [Article III] standing," prudential standing is "'founded in concern about the proper – and properly limited – role of the courts in a democratic society.'" *Bennet v. Spear*, 520 U.S. 154, 162 (1997) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) and *Warth v. Seldin*, 422 U.S. 490, 498 (1975)). To satisfy these prudential standing concerns "a plaintiff's grievance must arguably fall within the zone of interests protected or regulated by the statutory provision or constitutional guarantee invoked in the suit." *Id.*; see also *National Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479, 492 (1998).

Here, the interests PhRMA seeks to advance are two-fold. First, drug manufacturers desire to ensure that Medicaid reimburses for their drugs without requiring prior authorization. Second, drug manufactures would like to avoid paying rebates in connection with purchases by Maine residents not covered by Medicaid or private insurance.

PhRMA lacks prudential standing, however, because neither concern is within the zone of interests protected or regulated by the Supremacy Clause or Medicaid.[4] The

[4] Prudential standing is a live issue in this case because the First Circuit addressed it without accepting PhRMA's argument that Maine had waived the issue by not arguing it in the district court. Pet. Rep. 5. The district court itself noted that Maine was free to raise the issue in proceedings "on the merits after the preliminary injunction stage." J.A. 233.

Supremacy Clause does not provide the requisite zone of interests because it does not, by its own force, protect or regulate any interests. *Chapman v. Houston Welfare Rights Org.*, 441 U.S. 600, 613 (1979). See also *Dennis v. Higgins*, 498 U.S. 439, 450 (1991) and *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103, 107 (1989). The Supremacy Clause merely gives "priority" to interests that are separately protected or regulated by a federal law whenever they come in conflict with state law. PhRMA must look to the allegedly preempting federal statute to find an interest to support standing.

The federal statute, however, also does not supply the requisite interest. First, Medicaid protects the interests of patients, not the interests of pharmaceutical manufacturers in maintaining a particular market share. See *Tap Pharmaceutical v. U.S. Dep't of Health & Human Servs.*, 163 F.3d 199, 208 (4th Cir. 1998) (manufacturer's financial interest in improving the market share of its product does not fall within the zone of interests protected by Medicare). The only relevant mention of drug manufactures in the Medicaid statute is in the rebate provisions, which are intended to ensure that manufacturers do not overcharge Medicaid, as Congress determined they had been doing prior to 1990. See *Pharmaceutical Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 225 (D.C. Cir. 2001) (discussing origins of rebate provision).

Second, Medicaid does not regulate the pharmaceutical industry. The rebate provisions simply establish the price discounts that the federal government demands in its role as a purchaser of prescription drugs. Manufacturers agree to those provisions only to the extent they wish to avail themselves of the Medicaid market. Such provisions are not enforced against them in the same manner

as are, for instance, regulations under the Federal Food, Drug and Cosmetic Act. 21 U.S.C. 355.[5]

PhRMA attempts to supplement its tenuous claim to an "interest" under Medicaid by arguing (Pet. Rep. 6; Br. 23) that the Medicaid rebate provisions should not be judged on their face, but should be understood as part of a "*quid pro quo*" between drug manufacturers and Congress. That *quid pro quo*, the argument goes, gave the drug manufacturers an interest in ensuring that every Medicaid beneficiary has unrestricted access to every drug for which there is a Medicaid rebate agreement. Of course, a statute is not to be interpreted by the subjective understanding of a lobbying interest. More fundamentally, PhRMA's view cannot be squared with the statute. Medicaid has never prohibited the States from imposing limits and conditions on purchases of prescription drugs. In fact, the 1990 amendments specifically ratified the states' authority to control drug use by imposing prior authorization. 42 U.S.C. 1396r-8(d)(1)(A). Congress enacted the rebate provisions to stop drug manufacturers

[5] *St. Thomas-St. John Hotel & Tourism Ass'n v. Virgin Islands*, 218 F.3d 232, 238 (3d Cir. 2000) and *City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624 (1973), relied upon by PhRMA (Rep. Br. Opp. 5), do not advance the prudential standing analysis here because both cases involved comprehensive, federal regulatory schemes promulgated pursuant to Congress' powers under the Commerce Clause. Medicaid, enacted pursuant to Congress' spending powers, is not a comprehensive scheme for regulating the pharmaceutical industry.

from overcharging state Medicaid programs, not to endow drug manufacturers with new rights or interests.

Rejection of PhRMA's claim to standing would not create a safe-harbor for Maine Rx because the federal government is uniquely situated to enforce Medicaid's primacy through the power of its purse. "In legislation enacted pursuant to the spending power, the typical remedy for state noncompliance with federally imposed conditions is not a private cause of action for noncompliance but rather action by the Federal Government to terminate funds to the State." *Pennhurst State School and Hospital v. Halderman*, 451 U.S. 1, 28 (1981). See 42 U.S.C. 1396c. The two sovereign parties to the Medicaid "contract" are appropriately left to themselves to resolve any conflict that the Secretary perceives between Maine Rx and Medicaid, with judicial review, if any, of the Secretary's final decision on the matter available pursuant to the procedures set forth in 42 U.S.C. 1316(a)(3).

II. MAINE RX IS NOT PREEMPTED BY MEDICAID

A. Maine Rx Does Not Contravene Medicaid's Primary Objective of Providing Medically Necessary Medicine to Medicaid Beneficiaries.

In Part I of its brief, PhRMA argues that the Maine Rx program is preempted not because it contravenes any express Medicaid provision but rather because it so conflicts with the objectives of Medicaid as to be unconstitutional on its face. Pet. Br. at 14-23. A presumption against preemption, particularly implied preemption, applies as "the States are independent sovereigns in our federal

system," and the Court has "long presumed that Congress does not cavalierly pre-empt" state law, "particularly . . . [when] . . . Congress has 'legislated in a field which the States traditionally occupied.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Protection of the health of their residents is undeniably a traditional responsibility of the States. Additionally, the case for inferring an intent on the part of Congress to prohibit or otherwise limit state behavior, and thus the case for preemption, is weakest when the allegedly preempting statute was enacted pursuant to Congress' spending powers under Article I, section 8 of the Consitution.

> [L]egislation enacted pursuant to the spending power is much in the nature of a contract: in return for federal funds, the States agree to comply with federally imposed conditions. The legitimacy of Congress' power to legislate under the spending power thus rests on whether the State voluntarily and knowingly accepts the terms of the 'contract.' There can, of course, be no knowing acceptance if a State is unaware of the conditions or is unable to ascertain what is expected of it. Accordingly, if Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously. By insisting that Congress speak with a clear voice, we enable the States to exercise their choice knowingly, cognizant of the consequences of their participation.

Pennhurst State School & Hospital, 451 U.S. at 17 (citations omitted); see also *New York State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405 (1973). Here, Congress did speak clear and in positive terms: "[a] state may subject to prior

authorization any covered outpatient drug." 42 U.S.C. 1396d(1)(A).

The test for implied preemption asks whether the challenged state statute "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).[6] "Any conflict must be 'irreconcilable . . . . The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute.'" *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 110 (Kennedy, J., concurring in part and concurring in the judgment) (quoting *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982). And it is not sufficient to show a conflict with some subsidiary provision of Medicaid – PhRMA must show "direct contradiction" with one of Medicaid's "*primary* objectives as conveyed with clarity in the federal legislation." *Gade*, 505 U.S. at 110 (emphasis added). Because "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case," *Medtronic*, 518 U.S. at 485 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)), the Court hews closely to the "explicit statutory language and the structure and purpose of the statute." *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990); see also *Gade*, 505 U.S. at 111 (Kennedy,

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[6] PhRMA agrees that this is the conflict preemption test, and has recast its "question presented" accordingly. *Compare* Br. i ("Whether the federal Medicaid statute . . . *precludes* Maine from limiting Medicaid patients' access to prescription drugs as a means of compelling drug manufacturers to subsidize discounts for non-Medicaid populations") (emphasis added) *with* Pet. i ("Whether the federal Medicaid statute . . . *allows* a state to use [prior authorization] authority under that statute. . . . ") (emphasis added).

J.) (admonishing that "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law."). By pressing a facial attack, PhRMA takes on "the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987); see also *California Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572, 579-80 (1987).

PhRMA makes no such showing. Although framed in a variety of ways, PhRMA's position distills down to the belief, without the support of any facts in the record, that Maine Rx will harm Medicaid beneficiaries. This belief is founded on the view that Maine Rx will inevitably "burden" doctors and state Medicaid administrators so as to deprive beneficiaries of the medicines they need. With no evidence to substantiate these beliefs, PhRMA's facial challenge fails as a matter of law.

The "burden" of prior authorization, moreover, is explicitly contemplated by Medicaid. It makes no difference whether prior authorization is imposed because a manufacturer refuses to participate in Maine Rx or for some other reason – the "burden" it places on patients and their physicians is the same in either case. PhRMA has identified nothing inherent in the Maine Rx prior authorization process that distinguishes it from prior authorization otherwise available to and utilized by states.

Thus, PhRMA has not and cannot present any evidence that Maine Rx's use of prior authorization will "harm" Medicaid beneficiaries any differently than prior

authorization in general will "harm" them. Maine, as it has pledged, will continue to abide by the time limitations set forth in the Medicaid statute. 42 U.S.C. 1396r-8(d)(5); J.A. 166-67. Maine will continue to provide all medically necessary prescription drugs in satisfaction of Medicaid's fundamental requirements. 42 U.S.C. 1396; J.A. 151, 167.

PhRMA's case, therefore, rests on a general disdain for prior authorization that Congress did not share.[7] Prior authorization, no matter why it may be imposed, does not contravene Medicaid because prior authorization is nothing more than a mechanism for testing whether a particular drug is "medically necessary." As the Court explained in *Beal v. Doe*, 432 U.S. 438, 444-45 (1977), "[a]lthough serious statutory questions might be presented if a state Medicaid plan *excluded necessary* medical treatment from its coverage, it is hardly inconsistent with the objectives of the Act for a State to refuse to fund *unnecessary* – though perhaps desirable – medical services." (emphasis added).

With the advent of multiple therapeutically equivalent medications in recent years, there is often no single

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[7] The pharmaceutical industry's vigorous opposition to prior authorization in general dates back to at least 1990 when it unsuccessfully lobbied against it. *Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 Before the Subcomm. on Health for Families and the Uninsured of the Senate Comm. on Finance*, 101st Cong., 2d Sess. 38, 139 (1990) (statements of Gerald J. Mossinghoff, president of the Pharmaceutical Manufacturers Association) (arguing that prior authorization should not be allowed by the Medicaid statute, and also warning that if Congress adopts the premise of therapeutic equivalence between some drugs it will create a system of "second-class medical care for Medicaid recipients.").

drug that is indispensable for treating a given patient. In the rare case that only one drug will suffice, the State will grant authorization and provide the drug regardless of whether it is manufactured by a company that participates in Maine Rx. Where, however, the health care professionals on Maine's Drug Utilization Review Committee have determined that multiple therapeutically sufficient therapies are available, no one of them is "medically necessary" within the meaning of Medicaid. In that case, it is simply irrelevant to Medicaid's primary purpose whether the doctor's second choice rather than first choice is prescribed. In fact, where the first choice is more expensive than the second choice, the *failure* to require prior authorizations would result in unnecessary expenditures of state and federal Medicaid funds.[8]

PhRMA goes on to theorize that Maine Rx will inevitably harm Medicaid patients by burdening doctors and state Medicaid administrators, and their ability to provide medically necessary medicine. Pet. Br. at 15-16. Both

[8] For instance, PhRMA-member company SmithKline Beecham, pointing to a study of the U.S. Centers for Disease Control and Prevention (CDC), asserts that prior authorization of Augmentin (its "flagship antibiotic") will harm children suffering from ear infections. J.A. 112, 104. But practicing Maine pediatrician Dr. H. Burtt Richardson prescribes "Augmentin as a *second line* drug after another drug, usually high dose amoxicillin, has failed to adequately treat an ear infection." J.A. 154 (emphasis added). Dr. Richardson's clinical judgment is based not only on the fact that "Augmentin is 3 to 6 times as expensive as amoxicillin," but also that "amoxicillin is effective in treating ear infections 80-85% of the time." J.A. 154. SmithKline's own 1999 annual report notes that the CDC "recommended *Augmentin* as a *second line* of defence when amoxycillin has failed." SmithKline Beecham plc, *1999 Annual Report* 22 (2000), also available at http://www.gsk.com/financial/financialreports.htm, Def. Opp. Mot. Prelim. Inj.; see note 5, supra. (second emphasis added).

doctors and Medicaid employees already handle prior authorization requests as a matter of routine, both for Medicaid and for third party payors. J.A. 149. If Maine Rx results in a marginal increase in those administrative tasks, that minimal "burden" does not rise to an "irreconcilable conflict" with the primary purposes of Medicaid. PhRMA certainly has failed to come forward with any evidence that as a result of such "burdens" Maine physicians will fail to conform with applicable standards of care[9] or that the State will fail to satisfy the safeguards Congress placed on prior authorization. PhMRA's facial challenge thus fails because PhRMA has not remotely demonstrated that Maine Rx cannot be implemented in a manner that will not harm Medicaid patients. *Salerno*, 481 U.S. at 745 (in a facial attack the "challenger must establish that no set of circumstances exists under which the Act would be valid.").

Finally, when seeking *certiorari*, PhRMA asserted that "no further development of the record would contribute to or alter the relevant legal analysis" of this case. Pet. at 2. Switching gears, PhRMA now proffers a "lodging" (Br. 6) containing new documents purporting to show that Medicaid patients were harmed when, independent of Maine Rx, Maine expanded its use of prior authorization in January, 2000 to make Medicaid more cost-effective.

[9] PhRMA's unsupported and cynical suggestion that Maine's physicians would rather lower their standard of care than comply with DHS prior authorization procedures is refuted by the actual experience of Dr. Richardson, a practicing Maine pediatrician who supports the use of prior authorization to "reduce the price of drugs to . . . patients who do not have drug insurance benefits and who might otherwise not be able to afford medications." J.A. 154.

PhRMA aims to prove too much: that prior authorization, in and of itself, for whatever purpose, is harmful. In any case, if all the proof of harm that PhRMA can muster is a single anecdote from a local newspaper article written in the first days of the expanded program, PhRMA's concerns should be disregarded. During the past two years Maine has collected extensive data on the success of its expanded prior authorization program, showing that a well-designed program can ensure access to all medically necessary drugs well within the time frames set by Medicaid. Accordingly, if these issues are litigated in the future in a trial court, the evidence will show that prior authorization has resulted in a variety of salutary effects, including a *decrease* in the rate of adverse drug reactions, without any evidence of harm to patients. At the very least, the resolution of a vigorously disputed factual issue such as the quality of care possible in a prior authorization program should not depend on an untested "lodging."

B. Maine Rx Advances the Goals Of Medicaid by Achieving Cost-Savings.

1. Preemption analysis focuses on whether a state statute significantly obstructs the goals of the federal statute. PhRMA's analysis, however, turns the Supremacy Clause on its head. PhRMA contends that Maine Rx must "advance" the purpose of Medicaid. Even if correct, PhRMA fails to meet even this more forgiving test because Maine Rx advances Medicaid in a number of ways.

At the most fundamental level, Maine Rx will provide medical assistance to persons of limited financial means – a Medicaid goal in itself. Pet. App. 13. Equally important,

Maine Rx will benefit Medicaid by helping control Medicaid costs, in at least three ways. First, prior authorization will have the effect of ensuring that Medicaid funds are used efficiently. Maine Rx can be expected to trigger prior authorization more often than previously. Whenever Maine Rx–induced prior authorization requirements are imposed on a particular brand-name drug for which there exist less expensive therapeutic alternatives, Medicaid will save money because the less expensive drugs will be prescribed more often. The more often prior authorization is used, the more savings Medicaid will realize.[10]

Second, as the Secretary recognizes, providing benefits to those at the gates of Medicaid eligibility will ultimately benefit Medicaid itself. Pet. App. 13-14; U.S. Br. 28-30, 49a. Maine Rx will make prescription drugs more affordable for Maine's uninsured residents, enabling them to remain healthier and more productive. The alternative is deterioration in health, leading to unemployment, disability and, ultimately, full Medicaid eligibility, with adverse fiscal impact on an already stretched Medicaid program. *Id.*

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[10] It is well within the discretion of the Commissioner to impose prior authorization only on the most expensive drugs within a therapeutic class, even for those manufacturers that do not participate in Maine Rx. See 22 Me. Rev. Stat. Ann. § 2681(13), Pet. App. 92 (Commissioner may "coordinate" his administration of Maine Rx and Medicaid "in a manner that is advantageous" to both programs and which "enhance[s] efficiency, reduce[s] the cost of prescription drugs and maximize[s] the benefits" of all of the programs he administers).

A third way in which Maine Rx facilitates Medicaid cost-savings is by allowing the State to "serve as a pharmacy benefit manager." 22 Me. Rev. Stat. Ann. § 2681, Pet. App. 86.[11] Like that of a private sector PBM, the bargaining power of DHS is a function of the number of persons enrolled in the programs it administers. Currently, the Commissioner has authority to negotiate on behalf of the nearly 150,000 persons covered by Maine Medicaid. J.A. 182. That bargaining power expands greatly, however, when the Commissioner is authorized to negotiate on behalf of both Medicaid and the estimated 325,000 persons eligible for Maine Rx. J.A. 166. This enhanced bargaining power will redound to the benefit of Medicaid because, in addition to the rebates paid uniformly across the country, Medicaid authorizes Maine to negotiate supplemental rebates to further reduce the net cost of drugs to Medicaid. 42 U.S.C. 1396r-8(a)(1). Greater bargaining power leads to larger supplemental rebates and greater cost savings for Medicaid.

2. Although generally agreeing with Maine that keeping citizens from falling into Medicaid eligibility advances the goals of the program and that prior authorization is a valid means to achieve that end (U.S. Br. at 28), the federal government still hesitates to endorse Maine Rx. Two reasons are tendered. First, the government suggests that a "demonstration project" currently in effect

[11] Judge Keeton, writing in concurrence below, also saw the benefits of the State acting as a PBM, explaining "it would be a curious irony indeed if dozens of privately organized groups of Pharmacy Benefit Managers (PBMs) could participate freely in the market for purchasing products from pharmacy product manufacturers but States as guardians and trustees for their people could not." Pet. App. 39.

may achieve the same or similar beneficial results such that Maine Rx is rendered superfluous. U.S. Br. at 22-27.[12] While both Maine Rx and the demonstration project may serve generally the same population, the demonstration project has only been approved until 2006. Further, if PhRMA wins its separate legal challenge now pending in the Court of Appeals for the District of Columbia Circuit, the demonstration project would end overnight. More fundamentally, however, the government has pointed to no authority for the proposition that a program that does not conflict with a federal statute and in fact advances its purposes is somehow preempted because another program may produce similar beneficial results.

Second, the government and Maine part company over the size of the class of uninsured citizens who can be constitutionally encompassed in this type of program.[13] In

[12] Approximately two months after the district court enjoined Maine Rx, DHS applied to the Secretary for approval of a five-year Medicaid demonstration project testing an alternative price reduction program. The Secretary approved this "Healthy Maine Prescriptions" (HMP) program pursuant to 42 U.S.C. 1315(a) (authorizing demonstration projects), and it took effect on June 1, 2001. The HMP offers price discounts to persons not eligible for Medicaid but earning no more than 300 percent of the federal poverty level. PhRMA has separately challenged HMP on the grounds that it exceeds the Secretary's approval authority under 42 U.S.C. 1315(a). The district court granted summary judgment in favor of the Secretary and the Commissioner, and PhMRA has appealed. *Pharmaceutical Research & Mfrs. of Am. v. Thompson*, 191 F. Supp.2d 48 (D.D.C. 2002), appeal pending, No. 02-5110 (D.C. Cir.). Oral argument on the appeal is scheduled for December 5, 2002.

[13] The government also suggests that Maine Rx is invalid because Maine did not ask the Secretary for approval. This concern, however, arises out of the government's substantive problem with the breadth of Maine Rx. In any event, this issue is not properly before the Court, as the Solicitor General notes. U.S. Br. 29, n.11.

the opinion of the Solicitor, Maine Rx is flawed because it might help those who are not pressed up against the gates of Medicaid eligibility. U.S. Br. at 20-21, 29. This view itself is flawed, however, because no record has been developed as to how many, if any, "not-so-needy" uninsured persons will avail themselves of Maine Rx or what possible adverse effect including these persons could have on the Medicaid program. Indeed, their inclusion, if substantial, will benefit Medicaid in light of the PBM-like role Maine Rx creates for DHS. Maine's market power increases in direct proportion to the number of persons enrolled in both Maine Rx and its Medicaid program. In other words, Maine's ability to use prior authorization to negotiate better rebate agreements for both programs is enhanced by the enrollment of even those uninsured residents who may not fit within the Solicitor General's definition of the "most" needy. By combining the Maine Rx and Medicaid populations into a single purchasing pool, DHS will obtain the bargaining power of a far larger population than either program separately provides. This will enable the Commissioner to negotiate larger Medicaid discounts than the current Medicaid discount.

III. MAINE RX DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE.

A. Maine Rx Does Not Violate The Dormant Commerce Clause Because Congress Has Authorized The States To Use Prior Authorization.

The Constitution provides that "The Congress shall have power ... to regulate commerce ... among the several States...." Art. I, Sec. 8, Cl. 3 (Commerce Clause). Congress' express constitutional authority implies that the

states may not regulate commerce among the states. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 87 (1987) (recognizing "dormant" aspect of the Commerce Clause). Although the dormant Commerce Clause generally prohibits states from directly regulating interstate commerce, it does not prohibit the states from doing so if authorized by Congress. *Northeast Bancorp v. Board of Governors of the Fed. Reserve Sys.*, 472 U.S. 159, 174 (1985) ("When Congress so chooses, state actions which it plainly authorizes are invulnerable to constitutional attack under the Commerce Clause").

Maine Rx does not regulate interstate commerce for the reasons set forth in the following sections. But even if that is incorrect, Maine Rx does not violate the dormant Commerce Clause because Maine is only doing what Congress has authorized it to do: impose prior authorization in Medicaid. If Maine Rx-induced prior authorization advances the purposes of Medicaid at the same time that it helps provide discounts for persons ineligible for Medicaid – and the Solicitor General and the Secretary generally agree that Congress did authorize the states to use Medicaid prior authorization as leverage to negotiate such discounts – then whatever effect Maine Rx may have on interstate commerce is an effect that Congress has approved.

B. Maine Rx Does Not Discriminate Against Interstate Commerce.

The Court of Appeals observed that "PhRMA does not contend, nor did the district court find, that the Maine Act discriminates on its face or in its effects." Pet. App. 24-25. Nonetheless, PhRMA now asserts (Br. 35-39) that Maine

Rx constitutes economic discrimination against the wholesale business of pharmaceutical manufacturers. Although this Court's economic discrimination cases have generally involved state laws that either favored in-state producers over out-of-state producers, or in-state purchasers over out-of-state purchasers, PhRMA argues that the dormant Commerce Clause should not be so limited. According to PhRMA, any law that benefits in-state interests and burdens out-of-state interests is inherently unconstitutional, regardless of its effect on commerce or economic competition.

The essential purpose of the dormant Commerce Clause is to prevent States from enacting discriminatory policies. See *CTS Corp.*, 481 U.S. at 87; *Best & Co. v. Maxwell*, 311 U.S. 454, 455 (1940); see also Donald Regan, *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, 84 Mich. L. Rev. 1091, 1092 (1986) (dormant Commerce Clause cases "ha[ve] been concerned exclusively with preventing states from engaging in purposeful economic protectionism"). Economic discrimination is forbidden because it hinders national economic markets. See *General Motors Corp. v. Tracy*, 519 U.S. 278, 299 (1997); *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 127-28 (1978). The dormant Commerce Clause forbids the states from treating in-state economic actors more favorably than their out-of-state competitors. *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 340-41 (1989); *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 579 (1986). It does not, however, forbid all actions designed to give in-state actors an advantage in the marketplace, "but only action of that description *in connection with the state's regulation of*

interstate commerce." *New Energy Co. of Indiana v. Limbach*, 486 U.S. 269, 278 (1988) (emphasis in original).

As both the district court (Pet. App. 64) and the court of appeals (Pet. App. 24-25) found, Maine Rx is not protectionist within the meaning of these well-settled dormant Commerce Clause principles. Maine Rx does not "give [in-state] producers an additional tool with which to shore up their competitive position," *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 197 (1994), and "has no impact on the relative proportions of local and out-of-state goods sold . . . ." *Exxon*, 437 U.S. at 126 n.16. It is not a "clog upon the mobility of commerce," *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 527 (1935), and it does not tip the scales of trade in favor of in-state producers. In short, Maine has not "strip[ped] away . . . the competitive and economic advantages" of out-of-state industry in favor of in-state industry. *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 351 (1987). Indeed, it is difficult to conceive of a statute that is discriminatory under the dormant Commerce Clause where, as here, there is no in-state industry to favor. See *Exxon*, 437 U.S. at 125 (there can be no finding of economic protectionism in the absence of local producers).

PhRMA suggests (Br. 35-38) that Maine Rx is impermissibly protectionist even if it does not affect economic competition, simply because it helps in-state consumers while burdening out-of-state producers. But PhRMA's apples-to-oranges comparison has no basis in *Healy*, *Brown-Forman* or *Baldwin*. In those cases the Court focused on the challenged laws' differential treatment of *economic competitors*. In each case the state law had the purpose and effect of tilting the economic playing field, benefiting in-state businesses at the expense

of their out-of-state competitors. It was the state's attempts to co-opt the competitive advantages enjoyed by out-of-state interests vis-a-vis their in-state counterparts, and the resulting distortion of the marketplace, that offended dormant Commerce Clause principles.

The approach in Maine Rx is fundamentally different from the price control schemes in *Healy*, *Brown-Forman* and *Baldwin*. Maine Rx seeks lower prices by wielding Maine's Medicaid purchasing power, not by "co-opting" the relative advantages of purchasers in other states.[14] Unlike the measures challenged in the price-control cases, Maine Rx always leaves manufacturers free to charge whatever prices they wish. Maine has only done precisely what *Brown-Forman* specifically allows: "[A] State may seek lower prices for its consumers, [so long as it does] not insist that producers or consumers in other States surrender whatever competitive advantages they may possess." *Brown-Forman*, 476 U.S. at 580.

PhRMA's reliance on *West Lynn* is misplaced. Like the other movement-of-goods cases, the analysis in *West Lynn* focuses on the impact of the challenged state law on out-of-state economic actors *vis-a-vis their in-state competitors*. *West Lynn* invalidated a Massachusetts law that was plainly designed to shore up local industry. The revenue from a state tax on wholesale domestic and imported milk was transferred to in-state milk producers, allowing them to reduce their prices and secure a competitive advantage

[14] It is ironic that PhRMA relies exclusively on decisions that prohibited states from "leveraging" out-of-state markets, given that the entire first half of PhRMA's argument complains that Maine Rx leverages the in-state Medicaid market.

against the more efficient out-of-state farms. The Massachusetts pricing scheme offended the dormant Commerce Clause because it had the purpose and effect of improving the competitive position of Massachusetts dairy farmers and reducing the market share of out-of-state farmers.

PhRMA cites *West Lynn* for the proposition that the dormant Commerce Clause prohibits states from burdening "'any part of the stream of commerce – from wholesale to retailer to consumer.'" Pet. Br. 38 (quoting *West Lynn*, 512 U.S. at 202). From that passage PhRMA concludes that a statute that burdens out-of-state producers is unconstitutional regardless of whether it benefits in-state producers. But the entire analysis in *West Lynn* hinged on the milk pricing order's unfair "advantage to in-state *producers*." 512 U.S. at 197 n.14 (emphasis added). The Court would not have found the Massachusetts law impermissibly protectionist if the revenues had been used for the benefit of *dealers* rather than *producers*:

> If the taxes were refunded only to the dealers, there might be no impact on interstate commerce, because the dealers might not use the funds to increase the price or quantity of milk purchased from Massachusetts dairy farmers. The refund to the dealers might, therefore, result in no advantage to in-state producers. On the other hand, by refunding monies directly to the dairy farmers, the pricing order ensures that Massachusetts producers will benefit.

Id. If the state may pay a subsidy to dealers, then surely a subsidy to consumers, who are even farther down the

chain of distribution, would not infringe the dormant Commerce Clause.

West Lynn recognized that the dormant Commerce Clause is concerned with "*differential* burdens," that is, state laws that impose a greater burden on out-of-state economic actors than on their in-state competitors. 512 U.S. at 202-03 (emphasis added). PhRMA's notion (Br. 38) that any "burden" is impermissible regardless of its *differential* effect on economic competition requires a dramatic expansion of the dormant Commerce Clause and must be rejected. As one commentator has written, "not just any purpose to advantage local economic actors at the expense of foreign actors is protectionist." Regan, *supra*, at 1095. A state statute is protectionist only if "[t]he purpose [is] to advantage local actors at the expense of their foreign *competitors*." *Id.* (emphasis in original); see also *General Motors*, 519 U.S. at 300 ("In the absence of . . . competition between the supposedly favored and disfavored entities in a single market there can be no local preference . . . to which the dormant Commerce Clause may apply.").

PhRMA also contends (Br. 32-33) that Maine Rx is protectionist because it purportedly ties prices in Maine to *national* Medicaid prices. On that basis PhRMA analogizes Maine Rx to the "out-of-state price benchmark[s]" invalidated in *Brown-Forman* and *Healy*. Br. 33. But that argument also fails. Maine Rx on its face does not set the amount of manufacturer rebates, much less require rebates equal to rebates paid elsewhere. See W. Phelps, *Maine's Prescription Drug Plan: A Look into the Controversy*, 65 Alb. L. Rev. 243, 266 (2001) ("The Maine statute does not link Maine's prices to any other state"). Maine Rx rebates are negotiated, and until the injunction is lifted

any discussion of the level of the rebates and the form they might take would be wholly speculative. To be sure, the Act instructs the Commissioner to consider a variety of pricing information and then use his "best efforts" to negotiate an initial rebate equal to or greater than the Medicaid rebate. 22 Me. Rev. Stat. Ann. § 2681(4)(B). But mandating "best efforts" is a far cry from tying the rebates to out-of-state prices.[15]

Although PhRMA seems to regard the "best efforts" provision as tantamount to a mandated rebate level, the legislature recognized that the Medicaid rebate level was a target, not a requirement. The legislature understood that the Commissioner would have to enter real negotiations, and that the price reductions actually achieved by Maine Rx might be far less than those in Medicaid. That is why the Act details a system to measure the price reductions actually achieved by Maine Rx. See 22 Me. Rev. Stat. Ann. § 2693(1)(B). More significantly, if those price reductions prove inadequate, the Act imposes retail price controls directly on Maine pharmacies. *Id.* at § 2693(1)(B)(5). If, as PhRMA contends, Maine Rx rebates must equal national Medicaid rebates, there would have been no reason for the legislature to enact either the measurement provisions or the retail price controls.

Here, both the *amount* and the *form* of the rebate are left to negotiation. A manufacturer could propose a rebate

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[15] Assuming, arguendo, that Maine Rx did require rebates equal to Medicaid rebates, that still would not interfere with the commerce of any other state. Medicaid rebate amounts are uniform nationwide, and PhRMA cites no decision that has ever prohibited a state from tying prices to a national price as opposed to the price in another state.

unrelated to Medicaid rebates or any benchmark. For instance, a manufacturer could negotiate an agreement that provides a rebate of a fixed dollar amount rather than a percentage of a pricing index. Such agreements would leave the manufacturer free to adjust its Medicaid rebate amount – or any of its wholesale prices – without risk of violating Maine Rx. The Act therefore has no impact on markets or consumers in other states.

C. Maine Rx Does Not Control Commerce Beyond The State's Borders.

For non-discriminatory statutes such as Maine Rx the appropriate dormant Commerce Clause analysis requires PhRMA to show that the Act regulates the actual terms of commerce between out-of-state prescription drug manufacturers and their out-of-state wholesalers. Apparently recognizing this, PhRMA labors to show that Maine Rx "dictate[s] the terms on which buyers and sellers do business outside the state" and that it "necessarily changes the economic terms of [wholesale] transactions." Br. 27, 29.

Maine Rx simply will not do what PhRMA claims. Maine Rx only creates a system of quarterly rebate payments, the amount of which equals the product of the number of drugs of a participating manufacturer purchased by Maine Rx beneficiaries and the negotiated rebate amount for that manufacturer. As the Court of Appeals understood, this system "does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect." Pet. App. 22. The Solicitor General reached the same conclusion. U.S. Pet. Br. 17 (Maine Rx "does not regulate the terms of . . . out-of-state

transactions"). Maine Rx does not "dictate" the wholesale price, or prescribe the rule by which that price is determined. Such quarterly payments are not the actual "terms" of the transactions between manufacturers and wholesalers, and PhRMA's suggestion to the contrary is specious.

At the most fundamental level, Maine Rx has no extraterritorial application. The Maine Rx rebate is triggered only by retail sales within Maine, by Maine pharmacists, to Maine residents. Under Maine Rx, if none of a manufacturer's products is sold in Maine, the manufacturer has no obligation. The only "extraterritorial" aspect of the Maine Rx program is that it does not exempt products originating in other states from the rebate requirement. This does not turn Maine Rx into a direct regulation of drug manufacturers' wholesale transactions.[16]

This Court has never held that a state law impermissibly regulates interstate conduct merely because it has extraterritorial effects.[17] Indeed, contrary examples

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[16] PhRMA makes far too much of the fact that manufacturers sell through wholesalers, and that title to drugs passes from manufacturer to wholesaler before the drugs enter Maine. Br. 29. The goal of national economic union is not served by such formalistic considerations as the situs at which title passes. See *Exxon*, 437 U.S. at 127 (The Commerce Clause is not concerned about "the particular structure or methods of operation" of the market in question.).

[17] It is even open to question whether the "extraterritorial" branch of dormant Commerce Clause doctrine exists at all. Although some litigants have argued that the *Brown-Forman* prohibition on "directly regulat[ing]" interstate commerce would invalidate any regulation with extraterritorial effect, another panel of the First Circuit has noted that this Court has not applied *Brown-Forman* in that way. See *Grant's Dairy v. Comm'r of Maine Dep't of Agric., Food & Rural Resources*, 232 F.3d 8, 19 (1st Cir. 2000) (Selya, J.).

abound. See, *e.g.*, *CTS Corp.* 481 U.S. at 87-88 (upholding state anti-takeover law despite extraterritorial effects); *Exxon*, 437 U.S. at 125-29 (upholding state law prohibiting vertical ownership in the gasoline industry even though law had substantial impact on out-of-state companies); see also *K-S Pharmacies, Inc. v. American Home Products Corp.*, 962 F.2d 728 (7th Cir. 1992) (Easterbrook, J.) (upholding state law regulating wholesale drug prices despite extraterritorial impact). In the words of the Third Circuit, this Court "has never suggested that the dormant Commerce Clause requires Balkanization, with each state's law stopping at the border." *Instructional Sys., Inc. v. Computer Curriculum Corp.*, 35 F.3d 813, 825 (3d Cir. 1994).

PhRMA's parade of horribles (Br. 30-31) suggests that Maine and other states might "demand" rebates from out-of-state oil refiners or computer chip manufacturers on the basis of in-state sales of their products, and that "[s]uch schemes would obviously transgress the boundaries established by the Commerce Clause." *Id.* But Maine Rx provides for negotiated rebates and not "demands," and the State is hardly "regulating" commerce if the effort to collect rebates is backed only by the prospect of reduced government purchases. See *White v. Massachusetts Council of Constr. Employers, Inc.*, 460 U.S. 204 (1983) (municipal preferential purchasing policy is not a "regulation" of commerce). For example, when seeking to purchase new computers for State agencies, surely the State could favor those vendors that offer separate discounts to Maine school students. PhRMA's hypotheticals do not establish that "demanding" such concessions would hamper interstate markets, deprive economic actors in other states of

their competitive advantages, or constitute extraterritorial price regulation.

Nor can PhRMA (Br. 31-32) draw support from the interstate tax cases.[18] *Quill Corp. v. North Dakota ex rel. Heitkamp*, 504 U.S. 298 (1992) and its companions establish the test for whether the collection of taxes across state borders contravenes the dormant Commerce Clause. The inquiry focuses on the vendor's connection with the taxing state: If the vendor has no physical presence in the taxing state and only contacts customers by mail or common carrier, it lacks the requisite nexus to be taxed by that state. If, however, the vendor has even a "small sales force, plant or office" in the taxing state, 504 U.S. at 315, the tax does not infringe the Commerce Clause. Although by citing *Quill* PhRMA implies that drug manufacturers have no physical presence in Maine, that assertion is without record support. The extent of drug manufacturers' presence in Maine is a heavily fact-bound inquiry, and the sparse record on the preliminary injunction proceeding below is silent regarding such factors as the number of drug manufacturers' employees in Maine, which may be quite large.[19] PhRMA has failed to make "a clear showing that there are no in-state activities connected with sales."

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[18] PhRMA has never claimed that Maine Rx is in fact a "tax" or that the interstate tax cases are controlling. The federal district courts lack jurisdiction to enjoin state taxes. See 28 U.S.C. 1341 (Tax Injunction Act).

[19] Last year the pharmaceutical industry employed 87,892 sales representatives across the United States. See Chin, Tyler, *Drug Firms Score By Paying Doctors For Time*, Amednews.com, http://www.ama-assn.org/sci-pubs/amnews/pick_02/bil20506.htm. One must assume that many of these are in Maine.

American Oil Co. v. Neill, 380 U.S. 451 (1965), and *Quill* is therefore inapposite.

In addition, contrary to PhRMA's contention (Br. 31-32), Maine Rx would easily satisfy *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977), which held that state taxes may be applied to an activity with a substantial nexus with the taxing state. 430 U.S. at 279. The "activity" which triggers the Maine Rx rebate is retail sales activity within Maine. Although PhRMA repeatedly relies on the fiction that Maine Rx applies to wholesale transactions, only sales from Maine pharmacies trigger the rebate.

Finally, the Court should reject PhRMA's argument that Maine Rx should be invalidated because it supposedly burdens an entity without a political voice. Br. 37. Whether or not PhRMA and its member companies are formally represented in the Maine legislature, this highly organized and well-financed industry cannot seriously contend that its concerns are not heard in that body as well as Congress – the body with the constitutional authority to address both PhRMA's preemption and its Commerce Clause concerns. Moreover, numerous surrogates, including Maine doctors, patients and pharmacies, would be expected to speak out within Maine if any ill effects result from the prior authorization system that undergirds Maine Rx.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be affirmed.

Respectfully submitted,

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IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

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REPLY BRIEF OF PETITIONER

In its opening brief, PhRMA anticipated and addressed most of the arguments advanced by Maine in its answering brief. Here PhRMA responds to additional arguments raised by Maine, and to certain issues raised in the *amicus* brief of the United States.

I. THE MAINE RX PROGRAM CONFLICTS WITH THE FEDERAL MEDICAID STATUTE.

A. PhRMA Has Standing To Challenge Maine's Interference With The Federal Medicaid Program.

Maine cannot and does not dispute that PhRMA satisfies Article III standing requirements with respect to its Supremacy Clause and Commerce Clause challenges to the Maine Rx statute. PhRMA's members are threatened with immediate injury that is both directly attributable to the Maine Rx scheme and redressable by the courts. See *Northeastern Fla. Chapter of Associated Gen. Contractors* v. *City of Jacksonville*, 508 U.S. 656, 663-64 (1993).

Maine nevertheless seeks to avoid a ruling on the merits of PhRMA's Supremacy Clause claim by arguing that PhRMA does not have "prudential" standing to challenge Maine Rx's conflict with federal law. See Resp. Br. at 13-14. Maine's right to make this argument is in serious doubt, because Maine did not file a cross-petition to attack the First Circuit's determination that PhRMA has prudential standing.[1] Even if properly before the Court, Maine's argument lacks merit.

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[1] Absent a cross-petition, Maine may not pursue a claim that, if successful, would require vacatur, not affirmance, of the First Circuit's decision, and would give the state greater relief than it would obtain from affirmance on the merits. *See Northwest Airlines, Inc.* v. *County of Kent, Mich.*, 510 U.S. 355, 364-65 (1994) (barring, for failure to file cross-petition, respondent's challenge to court of appeals' finding of implied

This Court and lower federal courts have decided innumerable cases in which parties claiming to be injured by a state law have challenged it as preempted by federal law. See, *e.g.*, *Shaw* v. *Delta Airlines, Inc.*, 463 U.S. 85 (1983); *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978); *City of Burbank* v. *Lockheed Air Terminal Inc.*, 411 U.S. 624 (1973). Nothing about PhRMA's preemption challenge to the Maine Rx statute warrants a departure from the practice of deciding such cases. The First Circuit correctly held, consistent with other courts of appeals, that PhRMA has prudential standing to challenge the Maine Rx statute directly under the Supremacy Clause (Pet. App. 6-8).[2]

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right of action); *Mills* v. *Electric Auto-Lite Co.*, 396 U.S. 375, 381 n.4 (1970); *see generally El Paso Nat. Gas Co.* v. *Neztsosie*, 526 U.S. 473, 479-82 & n.3 (1999) (discussing and applying "firmly entrenched rule" against "modifying judgments in favor of a nonappealing party").

The First Circuit rejected Maine's prudential standing argument without deciding a similar, but distinct, question of whether Maine had waived the argument by failing to assert it in the district court (Pet. App. 6-8 & n.3). The First Circuit noted that the courts of appeals are divided as to whether a prudential standing objection is waivable. *Compare Pershing Park Villas Homeowners Ass'n.* v. *United Pac. Ins. Co.*, 219 F.3d 895, 899 (9th Cir. 2000) ("[A] party waives objections to nonconstitutional standing not properly raised before the district court."), *and Lindley ex rel. Lindley* v. *Sullivan*, 889 F.2d 124, 129 (7th Cir. 1989) (same), *with, e.g., Thompson* v. *County of Franklin*, 15 F.3d 245, 248 (2d Cir. 1994) (rejecting waiver), *and Community First Bank* v. *National Credit Union Admin.*, 41 F.3d 1050, 1053 (6th Cir. 1994) (same).

[2] *See St. Thomas-St. John Hotel & Tourism Ass'n* v. *Government of United States Virgin Islands*, 218 F.3d 232, 241 (3d Cir. 2000) ("a state or territorial law can be unenforceable as preempted by federal law even when the federal law secures no individual substantive rights for the party arguing preemption"); *Burgio & Campofelice, Inc.* v. *NYS Dep't of Labor*, 107 F.3d 1000, 1005-07 & n.2 (2d Cir. 1997) ("'[a] claim under the Supremacy Clause that a federal law preempts a state regulation is distinct from a claim for enforcement of that federal law,'" (alteration in original) (quoting *Western Air Lines, Inc.* v. *Port Auth.*, 817 F.2d 222, 225-26 (2d Cir. 1987))); *ANR Pipeline Co.* v. *Corporation Comm'n*, 860 F.2d 1571,

PhRMA's members are directly regulated by the statute it challenges here: Maine Rx. Furthermore, PhRMA's grievance falls squarely within the "zone of interests" that the Supremacy Clause protects—the guarantee against state statutes like Maine Rx that violate "the supreme Law of the Land." See generally *Association of Data Processing Serv. Orgs., Inc.* v. *Camp*, 397 U.S. 150, 153 (1970) (stating "prudential standing" test). As the First Circuit stated, "[i]n this type of action, it is the interests protected by the Supremacy Clause, not by the preempting statute, that are at issue" (Pet. App. 7). See generally *Ex parte Young*, 209 U.S. 123, 159-60 (1908); 13B Wright et al., *Federal Practice and Procedure* § 3566, at 24 (2d ed. Supp. 2002) ("The best explanation of *Ex parte Young* and its progeny is that the Supremacy Clause creates an implied right of action for injunctive relief against state officers who are threatening to violate the federal Constitution and laws.").

Maine's reliance on *Chapman* v. *Houston Welfare Rights Organization*, 441 U.S. 600 (1979), *Dennis* v. *Higgins*, 498 U.S. 439 (1991), and *Golden State Transit Corp.* v. *City of Los Angeles*, 493 U.S. 103 (1989), is misplaced. In those cases, the Court held that that a party seeking relief under 42 U.S.C. § 1983 must demonstrate an enforceable right under a federal statute with which a challenged state law is claimed to conflict. The Court's observations in those cases were made in considering claims for relief under § 1983 (including claims for damages), not claims for relief directly under the Supremacy Clause. The Court did not hold, and has not held, that a party directly claiming a Supremacy Clause violation must demonstrate an enforceable right under the preemptive federal law. To the contrary, the Court routinely entertains such actions. When a party challenges a state law as invalid under the Supremacy Clause, the interest sought to be

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1578-81 (10th Cir. 1988) (claim that state rules conflict with federal law "sufficient ... to indicate their claims come within the zone of interest protected by the Supremacy Clause").

vindicated is an interest created not by the preempting federal law, but by the Supremacy Clause—namely, the interest in being free from burdens imposed by a state law that the Supremacy Clause declares to be a nullity because it contravenes federal law. See *Green* v. *Mansour*, 474 U.S. 64, 68 (1985) ("[r]emedies designed to end a continuing violation of federal law are necessary to vindicate" Supremacy Clause interests); *Ex parte Young*, 209 U.S. at 159-60; cf., *e.g.*, *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978) (refinery operator permitted to lodge preemption challenge to state ordinance regulating design, size, and movement of oil tankers, without consideration of whether preempting statute granted right of action); *City of Burbank* v. *Lockheed Air Terminal Inc.*, 411 U.S. 624 (1973) (airport owner permitted to lodge preemption challenge to city ordinance regulating flight schedules, without consideration of whether preempting federal statute granted private rights). PhRMA therefore has prudential standing under the Supremacy Clause to assert its preemption challenge to the Maine Rx statute.

Maine is also incorrect in asserting that PhRMA would lack prudential standing to sue directly under the federal Medicaid statute—an issue that the First Circuit did not reach. The zone of interests test for prudential standing "is not meant to be especially demanding." *Clarke* v. *Securities Indus. Ass'n*, 479 U.S. 388, 399 (1987). A party need demonstrate only that the interest it seeks to protect "is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Camp*, 397 U.S. at 153.

Even if PhRMA were required to show prudential standing under the Medicaid statute, PhRMA's members' interests more than satisfy this limited requirement. PhRMA's members are both "regulated" and "protected" by the Medicaid drug assistance program. Like the states, manufacturers that choose to participate in the Medicaid prescription drug program must comply with the program's regulatory requirements, including the requirement to make

Medicaid rebate payments, or face significant penalties. See 42 U.S.C. § 1396r-8(b)(3), (4) (outlining civil penalties and possibility of termination for noncompliance); cf. *Wilder* v. *Virginia Hosp. Assoc.*, 496 U.S. 498, 502 (1990); *Alexander* v. *Choate*, 469 U.S. 287, 289 n.1 (1985).[3] The Medicaid prescription drug program also protects manufacturers. The statute promises manufacturers that Medicaid will cover their drugs if they agree to pay the rebates specified by Congress. The statute also limits—both directly, through restrictions on formularies and prior authorization, see 42 U.S.C. § 1396r-8(d)(4), (5), and indirectly, through the overriding requirement that the state act in the "best interests" of Medicaid recipients, see *id.* § 1396a(a)(19)—a state's ability to restrict coverage of the drugs of participating manufacturers. PhRMA's members have substantial interests in ensuring that their drugs are made available to Medicaid beneficiaries, and that Medicaid rebate payments are made to the states on such drugs as are dispensed, in a manner consistent with the letter and purpose of the Medicaid drug program.

In short, PhRMA has "prudential standing" to challenge the Maine Rx statute, under both the Supremacy Clause and (if need be) the federal Medicaid statute.[4]

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[3] Maine's suggestion that only Maine and the federal government, the "two sovereign parties to the Medicaid 'contract,'" *see* Resp. Br. at 17, should be permitted to resolve Medicaid conflicts does not alter this conclusion. Claims arising out of Spending Clause legislation do not sound purely in contract, *see Barnes* v. *Gorman*, 122 S. Ct. 2097, 2102 n.2 (2002), and private parties may raise Supremacy Clause challenges under such legislation, *see e.g. Blum* v. *Bacon*, 457 U.S. 132, 145-46 (1982); *Carleson* v. *Remillard*, 406 U.S. 598, 604 (1972); *Townsend* v. *Swank*, 404 U.S. 282, 285 (1971).

[4] Even if PhRMA's "prudential standing" could be drawn into question, the circumstances of this case would argue strongly in favor of full adjudication of the case. Maine does not contest PhRMA's standing (constitutional or prudential) to advance its Commerce Clause challenge to the Maine Rx statute. Inevitably, then, the Court will be obliged to pass

B. Maine Rx Prior Authorization Frustrates Congress's Medicaid Objectives.

It is undisputed that under Maine Rx, Maine will be using a Medicaid procedure (prior authorization), administered by the Medicaid program using Medicaid funds, to restrict Medicaid patients' access to (and hence the sales of) certain Medicaid-participating manufacturers' drugs, unless those manufacturers pay for the Maine Rx program for other state residents.

Maine argues that Maine Rx is not preempted because the prior authorization power that Congress gave the states in the Medicaid statute need not serve that statute's objectives. See Resp. Br. at 21 (asserting that "[p]rior authorization, no matter why it may be imposed, does not contravene Medicaid"). Alternatively, Maine asserts that Maine Rx does serve federal ends, see *id.* at 24-28, such that the state law is not preempted. As the Solicitor General observes, however, the Maine program's use of prior authorization burdens Medicaid recipients, and a state may not "act contrary to the interests of Medicaid recipients as a whole to achieve goals *unrelated* to the Medicaid program." U.S. Br. at 20. Maine Rx is invalid because it burdens Medicaid and Medicaid recipients for the express purpose of assisting the non-Medicaid population of Maine.

Congress did not give states the power to restrict Medicaid patients' access to drugs in the service of non-Medicaid objectives. To the contrary, Congress expected states to use prior authorization in the "best interests of the [Medicaid] recipients," 42 U.S.C. § 1396a(a)(19), and in ways that demonstrably benefit the Medicaid program, see H.R. Rep.

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on the validity of the state law. It would be passing strange to invoke a discretionary doctrine of judicial economy, *see Bennett* v. *Spear*, 520 U.S. 154, 162 (1997), to refrain from reviewing a single claim in a case otherwise squarely before the Court. Certainly, no "prudential" interest would be served by such an approach.

No. 101-881, at 98 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2110. Maine claims unfettered power to require prior authorization, bound only by the limitations set forth in 42 U.S.C. § 1396r-8(d)(5) itself. But this crabbed interpretation ignores the obligation to read the Medicaid statute, like any other statute, as a whole. See *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000) ("a reviewing court should not confine itself to examining a particular statutory provision in isolation" but must instead "interpret the statute as a symmetrical and coherent regulatory scheme") (internal quotation marks omitted).

Prior authorization by definition burdens Medicaid patients' access to (and hence manufacturers' sales of) prescription drugs. That burden alone, when imposed for non-Medicaid purposes, is sufficient to sustain PhRMA's preemption challenge.[5] Contrary to Maine's contention, PhRMA need not establish "that Maine Rx cannot be implemented in a manner that will not harm Medicaid patients." Resp. Br. at 23. Actual clinical harms to the health of Medicaid patients would of course amply demonstrate Maine Rx's conflict with Medicaid, but the statute's facial restrictions on access to drugs are more than sufficient.[6]

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[5] Maine's repeated invocation of *United States* v. *Salerno*, 481 U.S. 739 (1987), and its "no set of circumstances" test for facial challenges, *id.* at 745, is in vain. It is, of course, an open question whether *Salerno* properly states the standard in the first place. *See City of Chicago* v. *Morales*, 527 U.S. 41, 55 n.22 (1999) (plurality opinion). Even if it does, *Salerno*'s standard is satisfied here: Maine Rx-triggered prior authorization burdens Medicaid for non-Medicaid purposes, and thus conflicts with the federal statute, no matter how Maine may implement the prior authorization system.

[6] Maine suggests that because the procedural burden of Maine Rx prior authorization is the same as the procedural burden if prior authorization is required for Medicaid-related reasons, the Court should disregard its impact in this context. *See* Resp. Br. at 20-21. While the procedures may be the same regardless of the reason for imposing prior authorization, the magnitude of the burden they impose grows with each drug that is added

At the same time, Maine and its *amici* paint a benign picture of prior authorization, see Resp. Br. 22-24; AARP Br. at 19-23, that simply does not square with reality. Prior authorization cannot be merely a *de minimis* or innocuous procedural burden, as they suggest it is, if it is to have the powerful coercive effect on manufacturers that Maine intends. The *amicus* brief of several legal services organizations, filed on behalf of Medicaid beneficiaries and in support of neither party, is especially compelling in describing the reality of prior authorization. The brief explains that physicians, deluged by multitudes of ever-changing formularies and prior authorization requirements, not uncommonly prescribe drugs without seeking prior authorization. Even the most well-intentioned physicians may simply lack the information needed to pursue their patients' best interests. As a consequence, patients are denied coverage at the pharmacy counter, and they often receive inaccurate information about reasons for the denial.[7] See LSO Br. at 4-6. The *amicus* brief also notes that physicians aware of prior authorization requirements self-censor their prescriptions away from cutting-edge drug therapies, to the potential detriment of their patients. See *id.* at 6-7. Furthermore, these burdens are tremendously magnified for Medicaid patients, who frequently lack the financial and physical resources to navigate the prior authorization system and may simply

to the prior authorization list. Drugs that were previously readily available to Medicaid patients will now be restricted for no Medicaid reason. Indeed, if is to have the necessary coercive effect for Maine Rx purposes, prior authorization must be imposed on many drugs that were not previously subject to it, and it must be a substantial obstacle to prescription and sales of those drugs.

[7] For this reason, the data offered by *amici* in support of Maine suggesting that Maine's current prior authorization program promptly approves most requests, *see* MCSC Br. at 15-16 (citing lodging), is beside the point. Harmful consequences of prior authorization occur long before any such request is processed through the Medicaid system, if indeed it is ever submitted.

forego altogether the drugs their physicians prescribe.[8] See *id.* at 8-11.

Also without merit are Maine's contentions, in the alternative, that Maine Rx actually serves the Medicaid program. Maine makes three arguments, the first and third of which are freshly minted at this late date in the litigation, and all three of which are unpersuasive. First, Maine contends that the increased use of prior authorization, although implemented for Maine Rx purposes, will result in cost savings for the Medicaid program. See Resp. Br. at 24-25. This assertion lacks support. Prior authorization of a drug under Maine Rx is entirely unrelated to the drug's cost to the Medicaid program. It is just as likely *a priori* that manufacturers of more expensive drugs would participate in Maine Rx, while manufacturers of less expensive drugs for the same condition would not. Maine could well find itself deterring the prescription of inexpensive drugs through prior authorization, while readily covering expensive ones because the latter's manufacturers have bowed to the Maine Rx demand. In any event, no cost savings to Medicaid can be assumed.[9]

Second, Maine reiterates the First Circuit's contention that Maine Rx serves Medicaid because it may keep individuals close to the Medicaid eligibility threshold from becoming poor enough to qualify for Medicaid. See *id.* at 25. As

[8] For example, the State of Florida, in defending its Medicaid prior authorization system against a challenge by Medicaid beneficiaries, has furnished evidence that, as a consequence of prior authorization requirements, in a single month over 35,000 prescriptions were initially denied coverage, and for nearly 22,000 of those, Medicaid beneficiaries ultimately received no drugs at all in the same therapeutic class. *See Hernandez* v. *Medows*, 209 F.R.D. 665, 669 (S.D. Fla. 2002).

[9] To the extent that Maine's anticipated savings derive from Medicaid patients who are deterred from obtaining prescription drugs altogether, *see, e.g.*, note 8 *infra*, this rationale in fact highlights, rather than shields, the Maine Rx program's infirmities.

explained in PhRMA's opening brief at 25-26, this argument proves too much. By Maine's reasoning, pharmaceutical manufacturers could be forced to fund virtually any public assistance or welfare program because it might have the same kind of Medicaid "benefit." The Solicitor General also explains that Maine Rx reaches too broadly to support a credible claim of being directed to those at the Medicaid gates. See U.S. Br. at 20-22.

Finally, Maine suggests that Maine Rx will enhance the state's bargaining power if and when it negotiates with drug manufacturers for "supplemental" Medicaid rebates. See Resp. Br. at 26. PhRMA disputes Maine's premise that the federal Medicaid statute permits states to seek such rebates in the first instance, see, *e.g.*, *PhRMA* v. *Thompson*, No. 02-CV-1306 (D.D.C. filed June 28, 2002) (motion for preliminary injunction pending), and whether a state may do so is a question not before the Court in this case. In any event, a hypothetical marginal benefit to Medicaid in the event Maine later pursues this suspect, indirect strategy is inadequate to offset or justify Maine Rx prior authorization's immediate burden on the Medicaid program and its patients.

Maine's analogy to private sector pharmacy benefits managers ("PBMs") is itself flawed, because Maine is not negotiating on behalf of Maine Rx participants: it is mandating by statute that manufacturers make payments to benefit them. There is no room for market-based negotiation when one party is compelled by law to "enter into" the agreement on dictated terms. See 22 Me. Rev. Stat. Ann. § 2681(3) (Pet. App. 87).

C. Review In This Case Of Programs Other Than Maine Rx Would Be Inappropriate.

The Solicitor General agrees with PhRMA that the Maine Rx program conflicts with the federal Medicaid statute, because it "burdens the ability of Medicaid recipients to

obtain covered drugs while failing to serve Medicaid-related goals." U.S. Br. at 19.

The Solicitor General goes on, however, to invite the Court's attention to several additional issues that are not presented in this case, and that are the subject of other pending litigation—including a petition for a writ of certiorari now pending in *PhRMA* v. *Medows*, No. 02-__ (U.S. filed Dec. 5, 2002), involving a challenge by PhRMA to a Florida Medicaid program. Because none of these issues is before it in this case, the Court should resist the Solicitor General's invitation, and not opine on the validity of other state Medicaid programs and exercises of federal authority not implicated here.

First, the Solicitor General invites the Court to ratify an interpretation of the Medicaid statute that would give the states sweeping authority to impose, and the Secretary of HHS to authorize, prior authorization requirements for the purpose of extracting from manufacturers Medicaid rebates greater than those specified in the federal statute. See U.S. Br. at 15-18. This statutory issue, as the Solicitor General recognizes, is the subject of pending challenges to programs in Florida and Michigan. See *Medows*, No. 02-__ (U.S.); *Thompson*, No. 02-CV-1306 (D.D.C). Indeed, the Solicitor General even takes this opportunity cursorily to present and defend the government's litigating positions in those cases. U.S. Br. at 16-18.[10] However, the instant case raises none of

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[10] In the same vein, the Solicitor General invites the Court's attention to recent "advice" from HHS' Center for Medicare and Medicaid Services to state Medicaid directors setting out HHS' positions with regard to supplemental Medicaid rebate agreements, compliance of prior authorization requirements with clinical drug formulary safeguards, and leveraging of Medicaid prior authorization for non-Medicaid populations. *See* App. to U.S. Br. at 45a-50a. This letter, issued only two days before the filing of the U.S. brief, is a *post hoc* ratification of the government's litigating positions in the actions described herein, and, as an advisory communication, is not entitled to deference in any event. *See United*

those issues. The issue here is whether Maine may use Medicaid prior authorization to finance a *non*-Medicaid program. Florida's and Michigan's use of suspect regulatory devices (including but not limited to prior authorization) to obtain additional rebates for drugs purchased within the Medicaid program is not at issue. The statutory interpretation defended by the Solicitor General will soon be squarely before the Court in other cases, including PhRMA's petition in *Medows*, No. 02-___ (U.S.). Accordingly, the Court should decline the Solicitor General's invitation to opine broadly on HHS's authority to approve, and the states' power to implement, prior authorization programs in pursuit of "supplemental" Medicaid rebates. The only question presented here is whether a state may use Medicaid prior authorization to pursue *non*-Medicaid purposes.

Second, the Solicitor General endorses state Medicaid programs that, under the auspices of HHS's "waiver" or "demonstration project" authority, 42 U.S.C. § 1315(a), extend Medicaid prescription drug pricing to limited populations of otherwise Medicaid-ineligible patients. See U.S. Br. at 24-25. Again, the limits of the Secretary's authority to approve such programs is the subject of ongoing litigation. See, *e.g.*, *PhRMA* v. *Thompson*, 191 F. Supp. 2d 48 (D.D.C. 2002), *appeal pending*, No. 02-5110 (D.C. Cir. argued Dec. 5, 2002). The alleged statutory infirmities of those programs have no counterparts in the Maine Rx program. Again, the Court should refrain from speaking to the merits of programs whose statutory validity is not before it, and remains as yet unresolved by the lower federal courts.

Third, the Solicitor General announces here his view that HHS has the authority, if presented with a sufficient evidentiary record, to approve state programs that use

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States v. *Mead Corp.*, 533 U.S. 218, 228 (2001); *Christensen* v. *Harris County*, 529 U.S. 576, 586-87 (2000); *Bowen* v. *Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988).

Medicaid prior authorization as leverage to coerce manufacturer discounts and rebates for *limited* non-Medicaid populations. See U.S. Br. at 28-30. Maine has not sought, and HHS has not required it to obtain, federal Medicaid clearance for the Maine Rx program. Here, at least, the Solicitor General does acknowledge that there is no reason for the Court to consider the scope of this asserted authority. *Id.* at 30. Indeed, the Solicitor General's concession is an underinclusion: it is not only the scope, but also the very existence of such authority that should be left for another day.

II. THE MAINE RX REBATES VIOLATE THE COMMERCE CLAUSE.

In addition to but distinct from its Supremacy Clause infirmities, the Maine Rx statute violates the Commerce Clause by regulating extraterritorial commerce and discriminating against out-of-state commerce and consumers in favor of in-state interests. See Pet. Br. at 26-38.

Maine seeks to defend the Maine Rx statute on the ground that Congress has authorized the state to take action that might otherwise violate the Commerce Clause—specifically, to use Medicaid prior authorization to further the Maine Rx program. See Resp. Br. at 28-29. This argument necessarily presupposes that Maine Rx prior authorization is not preempted—which it is, for the reasons outlined above. And even if Maine's use of prior authorization is not preempted, it is Maine Rx's statutorily mandated rebate payments, not the use of prior authorization as a sanction for noncompliance, that violate the Commerce Clause. Congress has done nothing to shield Maine's demands for non-Medicaid rebates from Commerce Clause scrutiny. Although Congress can empower the states to enact legislation that would otherwise violate the Commerce Clause, it "must manifest its unambiguous intent before a federal statute will be [so] read." *Wyoming* v. *Oklahoma*, 502 U.S. 437, 458 (1992); *South-Central Timber Dev., Inc.* v. *Wunnicke*, 467 U.S. 82, 91-92 (1984) (Congress must "affirmatively contemplate" otherwise

invalid state legislation; no "implied" approval will be recognized).

Nor is there traction for Maine in its continued insistence that it is merely regulating (or by analogy, taxing[11]) "retail sales activity within Maine." Resp. Br. at 40. That contention ignores the fact that the manufacturers to whom the state will be sending Maine Rx bills are not engaged in that regulated activity. They are neither sellers nor buyers in the regulated transactions, or in any in-state sales leading to those transactions, and yet they are commanded to pay the state a "rebate" on those very sales. Perhaps Maine will next charge auto manufacturers for road tolls each time the cars they manufacture are driven on Maine highways, or send bills to cell phone manufacturers based on the number of minutes Maine residents spend talking on their phones in the state. Neither scenario is any more far-fetched than charging drug manufacturers each time someone else sells their products in Maine. Maine simply lacks that authority.

Maine's rebate scheme has the direct effect—not merely an ancillary one, cf. Resp. Br. at 37—of reducing the price received by the manufacturer in its out-of-state wholesale sales of drugs that ultimately cross pharmacy counters in Maine. Were the charge levied on, say, the retail pharmacy making an in-state sale to a Maine resident, with pricing pressure passed back up the chain of commerce to impact manufacturer's profits, the extraterritorial effects on manufacturers' commercial transactions might indeed be too indirect to support a Commerce Clause challenge. Here, however, the effect is direct: Maine charges the manufacturer,

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[11] The possibility that manufacturer's promotional representatives may be present in Maine does not upset this tax analogy. They could hardly supply the required "substantial nexus" between manufacturers and the "taxed" activity: Maine pharmacies' sales of drugs to Maine Rx participants. *See Complete Auto Transit, Inc.* v. *Brady*, 430 U.S. 274, 279 (1977). Manufacturers are simply not party to those "taxed" sales.

who as a result directly experiences a different price received for drugs that it has sold outside the state. Maine thus changes the economic terms of transactions occurring wholly outside its borders, a *per se* violation of the Commerce Clause under *Brown-Forman Distillers Corp.* v. *New York State Liquor Authority*, 476 U.S. 573 (1986), *Healy* v. *Beer Institute, Inc.*, 491 U.S. 324 (1989), and *Baldwin* v. *G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935).[12]

Maine's unquestioned power to regulate the terms of sale of entities that are engaged in in-state transactions does not justify its illicit effort to extend that authority beyond its borders. The "political check" that comes into play when a state seeks to tax or regulate "a significant group of state citizens" is lost when the state instead attempts to regulate outsiders. *West Lynn Creamery, Inc.* v. *Healy*, 512 U.S. 186, 200 & n.17 (1994) (internal quotation marks omitted). Commerce Clause limitations exist in part to prevent that result. *Id.*

Maine does not dispute the principle that the use of out-of-state price benchmarks is a *per se* violation under *Brown-Forman* and *Healy*. Such price tying violates the Commerce Clause because it deprives purchasers in other markets of their competitive advantages in dealing with drug manufacturers. See *Brown-Forman*, 476 U.S. at 580; *Healy*, 491 U.S. at 332-33. That dynamic will operate here as a consequence of Maine Rx, as manufacturers are forced to look beyond market conditions in California or Texas to the legal consequences of pricing decisions in those states for their pricing and payments in Maine. However, Maine seeks to shield the Maine Rx statute's price tying, 22 Me. Rev. Stat. Ann. § 2681(4) (Pet. App. 87-88), behind the statute's

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[12] Maine's suggestion that it is not affecting the "actual 'terms'" because the state will bill manufacturers quarterly and after the fact, while manufacturers make wholesale sales on an ongoing basis, *see* Resp. Br. at 36-37, is pure formalism.

instruction that the Commissioner use his "best efforts" to implement specified price benchmarks. Maine's argument ignores the coercive power inherent in the state's scheme, which eliminates the need for the Commissioner to exercise *any* "effort," best or otherwise, by commanding manufacturers to pay the rebates on pain of prior authorization, public condemnation, and even possible prosecution for profiteering.[13]

Finally, Maine Rx is protectionist and discriminatory in violation of the Commerce Clause because it externalizes the cost of a subsidy for local interests (namely, Maine Rx participants) onto out-of-state actors and their interstate commerce. See *West Lynn*, 512 U.S. at 202. The Commerce Clause does not, as Maine suggests, bar only protectionist regulation that advantages in-state interests against their out-of-state commercial competitors. See Resp. Br. at 30, 32. States can violate the Commerce Clause by advantaging not only their producers, but also their consumers, like the Maine Rx participants. See, *e.g.*, *Brown-Forman*, 476 U.S. at 580; *Camps Newfound/Owatonna, Inc.* v. *Town of Harrison*, 520 U.S. 564, 575-76 (1997). Indeed, the Court in *West Lynn* rejected just such an argument by Massachusetts that it could externalize the costs of a subsidy because the entities charged by the state were not commercial competitors of the in-state entities that received the subsidy. 512 U.S. at 202.

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[13] While certain profiteering provisions of the Maine Rx statute were preliminarily enjoined by the district court as applied to manufacturers' out-of-state sales (and Maine did not appeal that order (Pet. App. 5 n.2, 22 n.10)), others remain in force. Moreover, the very existence of the profiteering provisions evidences the coercive structure of the statute as a whole.

CONCLUSION

For the foregoing reasons and those stated in Petitioner's opening brief, the decision of the court of appeals should be reversed.

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In the Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PETITIONER

v.

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING REVERSAL

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QUESTION PRESENTED

The United States will address the first question presented in the petition (at i):

Whether the federal Medicaid statute, 42 U.S.C. 1396 *et seq.*, allows a state to use authority under that statute to compel drug manufacturers to subsidize price discounts on prescription drugs for non-Medicaid populations.[1]

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[1] This brief does not address the question whether the Maine Rx Program violates the Commerce Clause. The United States addressed that question in its brief (at 15-18) at the petition stage.

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INTEREST OF THE UNITED STATES

This case concerns whether the prior authorization provisions of the Maine Rx Program for prescription drugs are consistent with the federal Medicaid statute, which is administered by the Secretary of Health and Human Services. At the Court's invitation, the Solicitor General filed an amicus brief on behalf of the United States at the petition stage of this case.

STATEMENT

The Maine Rx Program at issue in this case is designed to encourage drug manufacturers to enter into a rebate agreement with the State that would require the manufacturer to provide a price discount for its drugs when purchased by *any* resident in the State. Absent such an agreement, the State, under its Medicaid program, will require Medicaid recipients to obtain prior authorization from the State before receiving an otherwise Medicaid-covered outpatient drug that is prescribed by a physician. This case presents the question whether the prior authorization feature of the

Maine Rx Program is unlawful under the Medicaid Act because it burdens Medicaid recipients in order to achieve goals unrelated to the Medicaid program.

A. Statutory Framework

1. The Medicaid program, established by Title XIX of the Social Security Act (the Medicaid Act), 42 U.S.C. 1396 *et seq.*, is a cooperative federal-state program that provides medical assistance to certain low-income individuals. *Harris* v. *McRae*, 448 U.S. 297, 301 (1980). The primary purpose of the Medicaid program is to "enabl[e] each State, as far as practicable under the conditions in such State, to furnish * * * medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. 1396.

In order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by the Centers for Medicare & Medicaid Services (CMS), which administers the federal Medicaid program on behalf of the Secretary of Health and Human Service (HHS). 42 U.S.C. 1396a. The state plan must specify, *inter alia*, the categories of individuals who will receive medical assistance under the plan and the specific kinds of medical care and services that will be covered. 42 U.S.C. 1396a(a)(10) and (17). If the plan is approved by the Secretary, the State is thereafter eligible for federal financial participation, *i.e.*, reimbursement by the federal government for a specified percentage of the amounts expended as medical assistance under the state plan. 42 U.S.C. 1396b(a)(1), 1396d(b).

States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. See *Alexander* v. *Choate*, 469 U.S. 287, 303 (1985). The Medicaid Act does, however, establish a number of prerequisites for approval of a state plan by the

Secretary. 42 U.S.C. 1396a(a)(1)-(65). Participating States are required to make medical assistance available to certain "categorically needy" persons. 42 U.S.C. 1396a(a)(10)(A)(i). At a State's option, a State may additionally make medical assistance available to "medically needy" persons. 42 U.S.C. 1396a(a)(10)(C); *Atkins* v. *Rivera*, 477 U.S. 154, 157-158 (1986). The Medicaid Act imposes income and resource limitations on many eligibility groups described in the statute. See, *e.g.*, 42 U.S.C. 1396a(a)(10)(A)(i)(IV), (VI) and (VII); 42 U.S.C. 1396b(f).

States are required to provide certain basic services, such as inpatient hospital care, to categorically needy individuals. 42 U.S.C. 1396a(a)(10)(A). The Act permits but does not require States to cover prescription drugs. 42 U.S.C. 1396d(a)(12). At least 44 States and the District of Columbia currently provide prescription drug coverage for categorically needy individuals, and 32 States and the District of Columbia provide such coverage for medically needy individuals. R. Schwalberg et al., *Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights* 4 (Oct. 2001). During 1998, more than 19 million Americans received medical assistance for prescription drug purchases under state Medicaid plans, at a cost exceeding $13.5 billion. Staff of House Comm. on Ways & Means, 106th Cong., 2d Sess. *2000 Green Book* 927 (Comm. Print 2000) (*Green Book*); see also *id.* at 924 (Table 15-21). Drugs purchased by Medicaid recipients account for roughly 10% of all prescription drugs purchased in the United States. *Ibid.*; accord *Pharmaceutical Research & Mfrs. of Am. (PhRMA)* v. *Thompson*, 191 F. Supp. 2d 48, 53 (D.D.C. 2002), appeal pending, No. 02-5110 (D.C. Cir. argument scheduled Dec. 5, 2002).

2. In 1990, Congress reviewed the prices being paid for prescription drugs under Medicaid. Congress determined that Medicaid was routinely paying more for prescription drugs than other large drug purchasers, particularly with

respect to single source drugs. H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). Congress concluded that "Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy." *Ibid.* Congress therefore decided to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." *Ibid.*

The rebate mechanism, enacted as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), Pub. L. No. 101-508, § 4401, 104 Stat. 1388-143, is codified as amended in 42 U.S.C. 1396r-8. State plans that provide medical assistance for covered outpatient drugs must comply with Section 1396r-8, and the Act generally prohibits federal financial participation "with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8." 42 U.S.C. 1396b(i)(10); see also 42 U.S.C. 1396a(a)(54) (requiring state plans to comply with Section 1396r-8). Section 1396r-8 provides that "[i]n order for payment to be available * * * for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement * * * with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer)." 42 U.S.C. 1396r-8(a)(1). The rebate obligation extends to all "covered outpatient drugs of the manufacturer * * * for which payment was made under the State plan." 42 U.S.C. 1396r-8(b)(1)(A).

If the drug in question is either a single source drug or an innovator multiple source drug, the rebate due on each unit paid for under the state plan is typically the difference between the average manufacturer price and the manufacturer's "best price," defined as the lowest price available from the manufacturer to any private purchaser or governmental entity within the United States, or 15.1% of average manufacturer price, whichever is greater. 42 U.S.C. 1396r-8(c)(1)(A), (B) and (C) and (c)(2). For other drugs, the rebate is 11% of average manufacturer price. 42 U.S.C. 1396r-8(c)(3). Drug manufacturers pay rebates to the state on a quarterly basis based on information provided by pharmacies as to the number of units of prescription drugs purchased by Medicaid recipients and covered under the state plan. 42 U.S.C. 1396r-8(b)(1)-(3), 1396r-8(k)(8). The state in turn reimburses pharmacies for the discounts that have been given on the manufacturers' prescription drugs. Approximately 500 manufacturers have entered into rebate agreements with the Secretary covering more than 56,000 drug products. 56 Fed. Reg. 7050 (1991) (setting forth rebate agreement between Secretary and drug manufacturers); http://cms.hhs.gov/medicaid/drugs/drughmpg.asp (list of manufacturers and drugs subject to Secretary's rebate agreement).

Once a drug manufacturer has entered into a rebate agreement with the Secretary (or, alternatively, a State) with respect to a covered outpatient drug, a State must cover that drug under the state plan unless the State complies with one of the provisions of the Medicaid Act that permits a State to exclude or restrict coverage. 42 U.S.C. 1396a(a)(54); H.R. Rep. No. 881, *supra*, at 97, 98. One such restriction is a prior authorization program. Section 1396r-8 provides that a state plan "may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available[,] * * * the approval of the drug before its dispensing for any medically accepted indication." 42 U.S.C. 1396r-8(d)(5). The Act further provides that "[a] State may subject to prior authorization any covered outpatient drug" only if the system providing for prior authorization "provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization," and "provides for the

dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation." 42 U.S.C. 1396r-8(d)(1)(A) and (d)(5).

A State may exclude or otherwise restrict the coverage of a drug where "the prescribed use is not for a medically accepted indication" or where expressly authorized by the rebate agreement. 42 U.S.C. 1396r-8(d)(1)(B)(i) and (iii). A State may also restrict from coverage or exclude altogether certain drugs, classes of drugs, or certain medical uses (such as drugs for weight control, fertility, hair growth, and smoking cessation). 42 U.S.C. 1396r-8(d)(1)(B)(ii) and (d)(2). In addition, a State may impose limits on minimum or maximum prescription quantities "to discourage waste," and "may address instances of fraud or abuse by individuals" as authorized under the Medicaid Act. 42 U.S.C. 1396r-8(d)(6).

In 1993, Congress amended Section 1396r-8 to permit States to maintain "formularies," *i.e.*, lists of covered drugs, under certain conditions. 42 U.S.C. 1396r-8(d)(1)(B)(iv). Under those amendments, an expert committee convened by the State may develop a formulary that excludes a covered drug "with respect to the treatment of a specific disease or condition" when "the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome * * * over other drugs included in the formulary." 42 U.S.C. 1396r-8(d)(4)(C). A State must permit coverage of a "drug excluded from the formulary," however, "pursuant to a prior authorization program" that complies with the Act. 42 U.S.C. 1396r-8(d)(4)(D). Congress explicitly provided that "[a] prior authorization program established by a State * * * is not a formulary subject to the requirements" of Section 1396r-8. 42 U.S.C. 1396r-8(d)(4).

B. Proceedings in this Case

1. In 2000, the Maine Legislature enacted the Maine Rx Program to reduce prescription drug prices for all Maine residents. Me. Rev. Stat. Ann. tit. 22, § 2681 (West Supp. 2001) (Maine Act). The program is open to all Maine residents, and is designed to allow enrollees to purchase prescription drugs from participating Maine pharmacies at a discounted price. Pet. App. 3; Maine Act § 2681(2)(F).

Under the Maine Rx Program, the State will reimburse pharmacies for such discounts out of a fund that is supported solely by rebate payments that the State collects from drug manufacturers. Maine Act § 2681(9); Pet. App. 3. The Maine Act provides that a drug manufacturer that sells prescription drugs in Maine through any publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the State. Maine Act § 2681(3). The Act directs the Commissioner of the Maine Department of Human Services to negotiate the amount of the rebate required, taking into consideration the rebate calculated under the federal Medicaid rebate program administered by the Secretary of HHS (see 42 U.S.C. 1396r-8(a)-(c), discussed at pp. 4-5, *supra*) and using his best efforts to obtain an initial rebate amount equal to or greater than that amount. Maine Act § 2681(4).

The Maine Act provides for the public disclosure of the names of manufacturers that do not enter into rebate agreements with the State. Maine Act § 2681(7). And as particularly relevant here, the Act directs the Maine Department of Human Services to "impose prior authorization requirements in the Medicaid program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers." *Ibid.*

2. Petitioner Pharmaceutical Research and Manufacturers of America (PhRMA) brought this action in the United States District Court for the District of Maine to challenge, *inter alia*, the prior authorization provisions of the Maine Rx Program as inconsistent with the Medicaid statute and the Commerce Clause. The district court entered a preliminary injunction barring the enforcement of the prior authorization

requirement against any drug manufacturer that does not enter into a rebate agreement with the State. Pet. App. 57-72.

The district court held that imposition of a prior authorization requirement under the state Medicaid program in this manner is inconsistent with the objectives of the federal Medicaid Act. Pet. App. 66-71. The court explained that the purposes of the Medicaid Act are to provide medical services, including prescription drugs, to individuals who are eligible for Medicaid, and observed that Congress thus has required that a state plan ensure that care and services will be provided in a manner consistent with "the best interests" of Medicaid's recipients. *Id.* at 67-68 (quoting 42 U.S.C. 1396a(a)(19)) (emphasis omitted). In the court's view, Maine may not impose a prior authorization requirement under its Medicaid program with respect to a drug manufacturer that does not enter into a rebate agreement covering persons who are not eligible for Medicaid, because Maine could not identify any Medicaid purpose that such a requirement would serve. *Id.* at 68. The court also concluded that the prior authorization provisions violate the Commerce Clause because "the practical effect of what Maine has done here is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine." *Id.* at 66.

3. The court of appeals reversed and vacated the preliminary injunction. Pet. App. 1-53. After determining that petitioner has standing to sue (*id.* at 6-8), the court rejected its arguments on the merits. The court perceived "no conflict between the Maine Act and Medicaid's structure and purpose" because the Maine Act requires compliance with the Medicaid program's specific requirements for a prior authorization program. *Id.* at 11 (citing 42 U.S.C. 1396r-8(d)(5)). The court also rejected petitioner's argument that it would be necessary to invalidate Maine's prior authorization provisions if they advanced no Medicaid purpose, concluding

that the absence of a Medicaid purpose "does not necessarily mean that the prior authorization scheme *conflicts* with the objectives of the Medicaid program." *Id.* at 12-13.

In addition, however, the court concluded that the Maine Rx Program does serve Medicaid purposes. In particular, the court concluded that the Maine Rx Program "furthers Medicaid's aim of providing medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical services,' 42 U.S.C. § 1396, even if the individuals covered by the Maine Rx Program are not poor enough to qualify for Medicaid." Pet. App. 13. The court noted that "there is some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures." *Ibid.* The court then reasoned that, "[w]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible." *Ibid.*

The court also rejected petitioner's contention that the Maine Act is unconstitutional under the Commerce Clause, concluding that it regulates activity that occurs in the State —the purchase of prescription drugs that triggers the rebate requirement, negotiation of rebate agreements, and prior authorization under the State's Medicaid program. Pet. App. 20- 23.

Judge Keeton filed a concurring opinion that stressed the difficulty of prevailing on a facial challenge. Pet. App. 31-53.

SUMMARY OF ARGUMENT

A. A State has broad discretion to subject any Medicaid-covered drug to prior authorization when such a requirement furthers the objectives of the Medicaid program. Congress passed the drug rebate provisions with an explicit grant of authority to "subject to prior authorization any

covered outpatient drug," as long as the State provides for a 24-hour response to a request for prior approval and for the dispensing of a 72-hour supply of the requested drug in an emergency situation. 42 U.S.C. 1396r-8(d)(1)(A) and (d)(5). Congress included those provisions to give States "the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." H.R. Rep. No. 881, 101st Cong., 2d Sess. 98 (1990). A State accordingly may establish a prior authorization program in order to reduce Medicaid costs for prescription drugs.

A State may not, however, implement a prior authorization program in order to advance non-Medicaid related goals. The drug rebate provisions, and the prior authorization provisions in particular, are designed to allow the State to strike an appropriate balance between the interests of Medicaid recipients in receiving covered prescription drugs of their physicians' choice and the interests of the Medicaid program as a whole in reducing expenditures for prescription drugs. That purpose of balancing various interests is frustrated by the use of a prior authorization program to further objectives that are unrelated to the Medicaid program.

The Maine Rx Program is therefore invalid because it is not designed to serve the interests of the Medicaid program. The program is open to all residents, and was enacted to lower prescription drug costs for all Maine citizens, regardless of financial or medical need. In these circumstances, the Maine Rx Program undermines congressional intent that a State will tailor its prior authorization program to achieve Medicaid-related goals.

B. In other situations, States may be able to rely on provisions in their Medicaid programs to assist in obtaining prescription drug benefits or discounts for non-Medicaid recipients, if the Secretary determines that such state initiatives sufficiently serve the objectives of the Medicaid program.

The Act grants the Secretary the authority to approve "any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives" of the Medicaid program. 42 U.S.C. 1315(a). Under that authority, the Secretary has approved demonstration projects by a number of States, including Maine, that provide prescription drug coverage to limited non-Medicaid populations, such as the low-income elderly. Because the Secretary regards the State's funding of such programs "as expenditures under the State plan," 42 U.S.C. 1315(a)(2)(A), a State's payment for a prescription drug under a demonstration project triggers the obligation of drug manufacturers to pay rebates under the federal Medicaid Act. 42 U.S.C. 1396r-8(b)(1)(A).

States may also be able to obtain drug discounts for certain low-income, albeit non-Medicaid populations, by using a prior authorization program to encourage drug manufacturers to extend rebates for drugs purchased by those populations. The Secretary has determined that any such program must be submitted to the Secretary under his regulations governing state plan amendments. App., *infra*, at 48a. The Secretary has explained that in submitting such a proposed amendment, the State should be prepared to demonstrate that it will "further the goals and objectives of the Medicaid program," such as "by making available to financially needy individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible." *Id.* at 48a-49a.

ARGUMENT

A STATE MAY REQUIRE PRIOR AUTHORIZATION FOR PRESCRIPTION DRUGS UNDER ITS MEDICAID PROGRAM IN ORDER TO ACHIEVE COST SAVINGS OR TO FURTHER OTHER MEDICAID-RELATED GOALS

Under the federal Medicaid program, States have broad discretion to tailor their Medicaid programs to meet the particular needs of their residents and their budgetary and other circumstances. *Alexander* v. *Choate*, 469 U.S. at 303; *Wisconsin Dep't of Health & Family Servs.* v. *Blumer*, 122 S. Ct. 962, 976 (2002). Accordingly, the Court has "not been reluctant to leave a range of permissible choices to the States, at least where the superintending federal agency has concluded that such latitude is consistent with the statute's aims." *Id.* at 975. That range of permissible choices is not, however, without its limits, and in this case the prior authorization feature of the Maine Rx Program exceeds those limits because it is not specifically designed to further any Medicaid purposes.

The court of appeals held that the prior authorization feature of the Maine Rx Program is not "preempted" by the federal Medicaid Act. But here, as in *New York State Department of Social Services* v. *Dublino*, 413 U.S. 405 (1973), the court below used the word "preemption" in a "rather special sense," for this case does not involve a claim of preemption of "a wholly independent state program dealing with the same or a similar problem." *Id.* at 411 n.9. Rather, Medicaid (like the Aid to Families with Dependent Children program in *Dublino*) "is a federal statutory program," and Maine's imposition of a prior authorization requirement under its Medicaid program necessarily is carried out "as part of the implementation of [Medicaid], and [is] therefore not wholly independent of the federal program." *Ibid.* Accordingly, the question is whether the prior authorization

provision of the Maine Rx Program is within the scope of the broad discretion that Congress afforded the States in fashioning their Medicaid plans. The Secretary of Health and Human Services is responsible for approving state plans and for the overall administration of the Medicaid program, and his position regarding the validity of the feature of the Maine Rx Program that is tied to the State's implementation of the federal Medicaid program is entitled to considerable deference. See *Dublino*, 413 U.S. at 421; see also, *e.g.*, *Blumer*, 122 S. Ct. at 976.

As explained below, the prior authorization provision of the Maine Rx Program is not within the scope of Maine's discretion under the Medicaid Act. "Where coordinate state and federal efforts exist within a complementary administrative framework, and *in the pursuit of common purposes*, the case for federal pre-emption [is] a less persuasive one." *Dublino*, 413 U.S. at 421 (emphasis added). Here, however, the prior authorization feature of the Maine Rx Program does not purport and is not tailored to further a Medicaid-related objective, such as preserving scarce Medicaid resources by making prescription drugs more readily available to low-income people and thereby reducing the prospect that they will become eligible for Medicaid. The Maine Rx Program is open to all Maine residents, whether rich or poor. Its prior authorization feature therefore is not "in pursuit of common purposes" with the federal Medicaid program. *Ibid.* Or, put in more traditional preemption terms, the prior authorization feature of the Maine Rx Program "stands as an obstacle to the accomplishment and execution of the full purposes and objectives" of the federal Medicaid Act, *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941), because it imposes on Medicaid beneficiaries the burdens of a prior authorization requirement without serving a countervailing Medicaid-related purpose.

The Secretary of HHS, through CMS, has recently sent a letter to State Medicaid Directors setting forth the Secre-

tary's interpretation of 42 U.S.C. 1396r-8 in several respects relevant to the issues in this case. Letter from Dennis G. Smith, Dir. of CMS's Center for Medicaid and State Operations, to all State Medicaid Dirs. (Sept. 18, 2002) (SMD Letter), App., *infra*, 45a-50a. That letter explains, *inter alia*, that a State's imposition of a prior authorization requirement under its Medicaid program to encourage the payment of drug rebates for non-Medicaid beneficiaries would constitute a material change in the operation of the state plan that must be approved by the Secretary as an amendment to the State's Medicaid plan. *Id.* at 48a. That letter further explains that a State must make an adequate showing that such an amendment would sufficiently further Medicaid-related purposes. *Id.* at 48a-49a. Because the Secretary has not yet approved any such state plan amendment, any questions concerning the scope of the Secretary's authority in that regard are not ripe for judicial review and are not before this Court in the present case. Any such questions may be addressed in a concrete setting in a future case in the event the Secretary approves a particular state plan amendment.

A. The Prior Authorization Provision Of The Maine Rx Program Is Invalid Because It Is Not Designed To Further A Medicaid-Related Purpose

1. *A State May Require Prior Authorization For Prescription Drugs In Order To Achieve Cost Savings Under Its Medicaid Program*

a. Before 1990, States had routinely required prior authorization for prescription or dispensing of drugs in order to control Medicaid costs. 136 Cong. Rec. 30,515 (1990) (noting the absence of any "federal laws or regulations governing prior authorization programs"); accord *Medicaid Prescription Drug Pricing: Hearing on S. 2605 Before the Subcomm. on Health for Families and the Insured of the Senate Comm. on Finance*, 101st Cong., 2d Sess. 17 (1990)

(statement of Rep. Wyden). In enacting the drug rebate provisions of Section 1396r-8 in 1990, Congress did not intend to upset that practice. Section 1396r-8 thus expressly permits a State to "subject to prior authorization any covered outpatient drug," but only if the State provides, first, for a 24-hour response to a request for prior approval, and, second, for the dispensing of a 72-hour supply of the requested drug in an emergency situation. 42 U.S.C. 1396r-8(d)(1)(A) and (d)(5). Congress recognized that those provisions would continue to give States "the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." H.R. Rep. No. 881, 101st Cong., 2d Sess. 98 (1990); accord *id.* at 95 (States "may * * * require prior authorization with respect to any of the prescription drugs which they elect to cover."), 98 ("[T]he bill would not affect any authority States have under current law to impose prior authorization controls on prescription drugs.").[2]

A State therefore has broad discretion to subject covered drugs to prior authorization in order to achieve cost savings for the Medicaid program, even though a prior authorization requirement may burden the ability of Medicaid recipients to obtain prescribed drugs. Such a program would further Congress's specific intent in enacting the prior authorization provisions to afford the States a mechanism to reduce Medicaid costs for prescription drugs, and would further the Act's requirement that state plans "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan * * *

[2] Section 4401(a)(3) of OBRA 1990, 104 Stat. 1388-143, provided that a State could not require prior authorization for new drugs approved by the Food and Drug Administration for a period of six months following FDA approval. In 1993, Congress deleted that restriction. Act of Aug. 10, 1993, Pub. L. No. 103-66, § 13602(a)(1), 107 Stat. 613.

as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care." 42 U.S.C. 1396a(a)(30)(A).

Applying those principles, the Secretary has approved state plan amendments submitted by Florida, Illinois, and Michigan, under which the State will generally require prior authorization under its Medicaid program for any drugs for which the drug manufacturer has not entered into a supplemental drug rebate agreement that provides for rebates for drugs prescribed to Medicaid beneficiaries in the State that are in excess of the rebates set forth in the manufacturer's rebate agreement with the Secretary.[3] Those initiatives "operate[] to drive down the cost of prescription drugs under the Medicaid program by providing drug manufacturers with a strong economic incentive to offer the state a supplemental rebate," which in turn "can directly improve the coverage and efficiency of the state Medicaid program." *PhRMA* v. *Meadows*, No. 02-10151J, 2002 WL 31000006 (11th Cir. Sept. 6, 2002), at *9; see SMD Letter, *infra*, 46a-47a ("A prior authorization program used to negotiate drug discounts for the Medicaid program is consistent with [Section 1396r-8] as well as the paramount purpose of the drug rebate provisions * * * to reduce the costs to the Medicaid program for prescription drugs.").

b. Petitioner has brought suits challenging the Florida and Michigan initiatives on two grounds. First, petitioner contends that a State lacks the authority to enter into a drug rebate agreement that supplements the national rebate agreement between the Secretary and the manufacturer, rather than supplanting the national agreement in that

[3] The Secretary currently is considering whether to approve similar state plan amendments submitted by Louisiana, Minnesota, Vermont, and West Virginia, and anticipates similar requests for approval from at least three other States.

State. Second, petitioner contends that the Florida and Michigan programs are not valid prior authorization programs, but rather in effect establish formularies that fail to comply with the requirement of 42 U.S.C. 1396r-8(d)(4)(C) that any drug excluded from a formulary be determined by an expert committee to lack "a significant, clinically meaningful therapeutic advantage * * * over other drugs included in the formulary."

Those contentions are without merit. Indeed, petitioner's challenge to Florida's plan amendment has been rejected by the Eleventh Circuit in *PhRMA* v. *Meadows*, *supra*.[4] The Act explicitly gives the Secretary the authority to approve a drug rebate agreement between a State and a drug manufacturer that sets forth the conditions on which Medicaid will make payment for a covered outpatient drug. 42 U.S.C. 1396r-8(a)(1) ("In order for payment to be available * * *, the manufacturer must have entered into and have in effect a rebate agreement * * * with the Secretary, on behalf of the States (except that, *the Secretary may authorize a State to enter directly into agreements with a manufacturer.*") (emphasis added). The Secretary accordingly has reasonably construed the Act—both in approving the amendments to the Florida, Illinois, and Michigan plans and in the September 18 letter to State Medicaid Directors—to permit a State to enter into either a separate rebate agreement or a supplemental rebate agreement with a drug manufacturer, as long as the result is to provide for drug rebates equal to or greater than the rebates set forth in the Secretary's national rebate agreement with the manufacturer. SMD Letter, *infra*, 45a-46a.

Furthermore, as the Secretary has also reasonably concluded, a State has the authority to establish a prior authori-

[4] Petitioner's challenge to the Michigan plan amendment has not yet been adjudicated. *PhRMA* v. *Thompson*, No. 02-CV-1306 (D.D.C. filed June 28, 2002).

zation program without meeting the requirements applicable to formularies. SMD Letter, *infra*, 47a. As discussed at pp. 14-15, *supra*, Congress in 1990 passed the prior authorization provisions of 42 U.S.C. 1396r-8(d)(1) and (5) to preserve the States' historic discretion to subject drugs to prior approval to contain Medicaid costs. The formulary provisions of Section 1396r-8(d)(4), which Congress added to the drug rebate provisions in 1993, gave States *additional* authority to exclude covered drugs, without modifying (much less detracting from) the States' well-established power to institute prior authorization programs. Indeed, when Congress added the formulary provisions of paragraph (d)(4), it expressly provided in the last sentence that "[a] prior authorization program established by a State under [42 U.S.C. 1396r-8(d)(5)] *is not a formulary* subject to the requirements of this paragraph." 42 U.S.C. 1396r-8(d)(4) (emphasis added); *PhRMA* v. *Meadows*, *supra*, at *3-*4, *10 (Section 1396r-8(d)(4)'s "unequivocal" last sentence "clarif[ies] that a prior authorization program and a formulary are distinct methods of restricting coverage of outpatient drugs"). The drug formulary provisions of the Act therefore furnish no basis for limiting a State's ability to establish a prior authorization program in order to obtain additional drug rebates for Medicaid recipients.

2. *The Medicaid Act Does Not Permit A State To Subject Drugs To Prior Authorization To Advance Goals Unrelated To The Medicaid Program*

A State's broad power to subject drugs to a prior authorization requirement, however, is not unlimited. In the Secretary's view, in addition to the Act's express 24-hour response and 72-hour emergency-supply requirements (42 U.S.C. 1396r-8(d)(5)), the Act contains a further limitation that a State will not use Medicaid's prior authorization provisions in order to further goals unrelated to the Medicaid program.

Congress did not intend that a State would require Medicaid beneficiaries to obtain prior authorization before obtaining covered prescribed drugs without serving *some* purpose related to Medicaid. For instance, Congress presumably did not intend that a State would leverage its Medicaid program to force a drug manufacturer to fund the State's transportation or education systems. Such an action would upset the balance struck by Congress in the prior authorization provisions between the interests of recipients in receiving medically necessary drugs and the interests of the States in ensuring that Medicaid pays for prescription drugs in an efficient and economical manner. H.R. Rep. No. 881, *supra*, at 98.

The court of appeals therefore erred in perceiving "no basis for inflicting the 'strong medicine' of preemption on a state statute that * * * merely fails to directly advance the purpose of the [Medicaid] program." Pet. App. 13. Maine's imposition of a prior authorization requirement is "part of the implementation of [Medicaid]," which is supported by substantial federal financial participation, not a "wholly independent state program." *Dublino*, 413 U.S. at 411 n.9. A State's prior authorization law that burdens the ability of Medicaid recipients to obtain covered drugs while failing to serve Medicaid-related goals would frustrate Congress's objectives under Section 1396r-8(d)(1) to allow a State to subject drugs to prior authorization in order to further the economic and efficient administration of *the Medicaid program*. Such a state law therefore would not be "in the pursuit of common purposes," *Dublino*, 413 U.S. at 421, with the federal Medicaid Act.

A Medicaid-purpose requirement under Section 1396r-8(d) is reinforced by the structure of the Medicaid Act. States participating in Medicaid must provide such safeguards as may be necessary to assure that covered services will be provided in a manner consistent with "the best interests of [Medicaid] recipients." 42 U.S.C. 1396a(a)(19). That provi-

sion, of course, does not limit the ability of States to determine the "amount, duration, and scope" of optional Medicaid benefits under a state plan (42 U.S.C. 1396a(a)(10)(B) and (C)(i)), or to take other action expressly provided for under the Act, including subjecting drugs to prior authorization (42 U.S.C. 1396r-8(d)(1)). And the "best interests" provision must be read in light of the other provisions of the Act that, *inter alia*, require a State to provide such procedures as may be necessary "to safeguard against unnecessary utilization" of services and to assure that payments are consistent with "efficiency, economy, and quality of care." 42 U.S.C. 1396a(a)(30)(A). The provision does, however, signal Congress's intent that a State will not act contrary to the interests of Medicaid recipients as a whole in order to achieve goals *unrelated* to the Medicaid program.

3. *The Prior Authorization Provision Of The Maine Rx Program Is Invalid*

The Maine Rx Program is invalid because it burdens Medicaid recipients without advancing Medicaid goals. Under the Maine Act, the State "shall impose [the] prior authorization requirements in the Medicaid program" on any "nonparticipating" drug manufacturer that does not enter into a rebate agreement with the State for drugs dispensed to *non*-Medicaid patients. Maine Act § 2681(7). The State program thus on its face is designed to serve the State's *non-Medicaid* population by imposing a burden on the ability of *Medicaid* recipients to receive an otherwise covered outpatient drug that is prescribed by a physician. Pet. App. 17.

The court of appeals reasoned that the Maine Rx Program could be sustained as furthering some purpose "related to Medicaid" because there was "some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures." Pet. App. 13. The state law, however, is not tailored to any Medicaid-related purpose of ensuring low-income individuals' ac-

cessibility to prescription drugs. The Maine Rx Program is open to all Maine residents, regardless of financial or medical need. *Id.* at 3; see 2000 Maine Acts, ch. 786 § A-5(2) ("It is the intent of the Legislature to provide access for *all* Maine citizens to medically necessary prescription drugs at the lowest possible prices.") (emphasis added). Nor does the Maine Act's statement of purposes reveal any Medicaid objective. *Id.* § A-5(3) (the law was enacted "to make prescription drugs more affordable for Maine residents, thereby increasing the overall health of our families, benefiting employers and employees and the fiscal strength of our society, promoting healthy communities and increasing the public health and welfare"). The Maine Rx Program thus undermines congressional intent that a State would not burden Medicaid recipients to achieve goals unrelated to the Medicaid program. See pp. 18-20, *supra*.[5]

The Maine Rx Program stands in contrast in this regard to a demonstration project that Maine has been conducting under the Secretary's special authority to approve an experimental state project that would permit non-Medicaid recipients to obtain drug discounts when the Secretary concludes that such a project "is likely to assist in promoting the objectives" of the Medicaid program. 42 U.S.C. 1315(a); see pp. 29-30, *infra*. The Maine demonstration project is specifically tailored to provide prescription drug discounts to financially needy non-Medicaid individuals with household incomes of

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[5] On October 5, 2000, Maine proposed implementing rules that would have required pharmacies to submit claims for reimbursement from the Maine Rx Program when "no other reimbursement option [is] available." J.A. 317. The proposed rules further stated that the Maine Rx Program "provides access to discounted prescription drugs only when the individual does not have a comparable or superior prescription drug benefit plan." J.A. 317. The proposed rules, however, contain no income limitations on eligibility, and set forth state residency as the only requirement for eligibility to participation in the Maine Rx Program. J.A. 311; see J.A. 307 ("The program allows *Maine residents* enrolled in the Program to purchase drugs at reduced cost.") (emphasis added).

up to 300% of the federal poverty level. See pp. 24-26, *infra*.[6] Maine residents who are eligible for benefits under this demonstration project would have no incentive to enroll in the Maine Rx Program because, according to CMS, the demonstration project appears to offer greater benefits. Thus, as a practical matter, the Maine Rx Program targets persons whose income is in excess of 300% of the federal poverty level. No Medicaid-related purpose is served by a state program focusing on that population. Especially in these circumstances, the Maine Rx Program exceeds a State's authority under Section 1396r-8(d) to subject drugs to prior authorization.

B. The Medicaid Act Does Not Prohibit A State From Relying On Provisions Of Its State Medicaid Plan To Promote The Availability Of Prescription Drug Benefits To Non-Medicaid Recipients If The Secretary Determines That Such An Initiative Would Further The Act's Objectives

The invalidity of the Maine Rx Program does not mean that States are powerless to invoke the Act's prior authorization provisions to enable non-Medicaid recipients to obtain more affordable drugs. The Medicaid Act affords the States broad latitude in implementing the Medicaid program, "at least where the superintending federal agency has concluded that such latitude is consistent with the statute's aims." *Blumer*, 122 S. Ct. at 975. Thus, the Act authorizes the Secretary to approve demonstration projects that require manufacturers to extend the Act's mandatory drug rebates to drugs purchased by individuals who are not otherwise eligible under Medicaid. In addition, a State may be able to demonstrate to the Secretary in a particular case that use of a prior authorization program under a state plan to benefit

[6] Currently, the federal poverty level under HHS's guidelines is $8860 for an individual and $18,100 for a four-member household. 67 Fed. Reg. 6932 (2002).

non-Medicaid populations is consistent with the purposes of the Medicaid program and therefore not prohibited.

1. The Secretary may authorize demonstration projects to provide Medicaid drug benefits to non-Medicaid eligible individuals

Nearly forty years ago, Congress recognized that the requirements of the Social Security Act "often stand in the way of experimental projects designed to test out new ideas." S. Rep. No. 1589, 87th Cong., 2d Sess. 19 (1962). Congress accordingly amended the Act to authorize the Secretary to approve "any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives" of various titles of the Act, including Title XIX, which governs the Medicaid program. 42 U.S.C. 1315(a). If the Secretary makes such a determination, he may "waive compliance with" any of the requirements of 42 U.S.C. 1396a, the provision that establishes the prerequisites for state Medicaid plans, "to the extent and for the period he finds necessary to enable such State * * * to carry out such project." 42 U.S.C. 1315(a)(1). The Secretary is also authorized, "to the extent and for the period prescribed by the Secretary," to regard any "costs of such project" that "would not otherwise be included as [state Medicaid] expenditures" "as expenditures under the State plan" that qualify for federal financial participation. 42 U.S.C. 1315(a)(2). As a matter of federal administrative policy, the Secretary will not approve a demonstration project unless it is budget-neutral with respect to the federal government, so that the federal government's costs over the life of the project do not exceed the contribution that the federal government would make to the State under the state Medicaid plan in the absence of the project. 59 Fed. Reg. 49,250 (1994). The Secretary has also stated that he will "[g]rant waivers to test the same or related policy innovations in multiple States," since "replication is a valid mecha-

nism by which the effectiveness of policy changes can be assessed." *Id.* at 49,249.

In a variety of contexts, the Secretary has approved demonstration projects under Medicaid to test the extension of benefits to certain individuals who are not otherwise eligible under Medicaid when the project is likely to assist in promoting the objectives of the Social Security Act. *E.g.*, http://www.cms.hhs.gov/medicaid/waivers/waivermap.asp (describing projects in Arkansas, Massachusetts, Minnesota, Missouri, Oregon, Rhode Island, Tennessee, and Wisconsin that extend managed care Medicaid benefits to certain non-Medicaid eligible individuals); http://www.state.me.us/bms/admin/sfy2000.pdf (describing Maine demonstration project that provides pharmacy and physician-assistant services to HIV-positive individuals with incomes not exceeding 250% of the federal poverty level).

As particularly relevant here, the Secretary also has authorized demonstration projects by a number of States to provide prescription drug coverage to limited non-Medicaid populations. Because the Secretary regards the costs of such projects "as expenditures under the State plan," 42 U.S.C. 1315(a)(2), a State's payment for a prescription drug under a demonstration project triggers the obligation of drug manufacturers to pay rebates under Section 1396r-8. 42 U.S.C. 1396r-8(b)(1)(A) (rebate payments must extend to "covered outpatient drugs * * * for which payment was made under the State plan").

Indeed, on January 18, 2001, the Secretary approved a demonstration project for Maine known as the "Maine Prescription Drug Discount Program" (now called the "Healthy Maine Prescriptions" or "HMP" program). The project consists of two components: (1) a "Low Cost Drugs for the Elderly or Disabled" (DEL) program, under which the State pays roughly 80% of certain prescription drug costs that exceed $1000 per year for elderly and disabled persons whose incomes do not exceed 185% of the federal poverty level, and

(2) a non-DEL component, under which the State pays two percent of the costs of non-DEL drugs purchased by persons with incomes below 300% of the federal poverty level.[7]

In addition to increasing the availability and affordability of prescription drugs to low-income individuals, Maine anticipated that its demonstration project would "provide important information on health status and utilization patterns of beneficiaries, as well as contribute to State public policy and planning." *PhRMA* v. *Thompson*, 191 F. Supp. 2d at 54. In approving the Maine project, the Secretary (acting through CMS's predecessor, the Health Care Financing Administration) determined that the project "is likely to assist in promoting the objectives of the Medicaid program." Letter from Robert A. Berenson, M.D., Acting Deputy Adm'r, to Kevin W. Concannon, Comm'r, Dep't of Human Servs. (Jan. 18, 2001). The Secretary explained that the program "would make prescription drugs more affordable to primarily low-income Maine residents who are not eligible for Medicaid," and "would allow these individuals to have affordable access to potentially life saving medicines." *Ibid.* The Secretary further explained that the inability to pay for needed pre-

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[7] Petitioner has brought suit challenging the non-DEL component of Maine's program, arguing, *inter alia*, that Maine's two-percent contribution to the project is an insufficient "payment * * * made under the State plan" to trigger the manufacturer's rebate obligations under 42 U.S.C. 1396r-8(b)(1)(A). Petitioner relies on the D.C. Circuit's decision in *PhRMA* v. *Thompson*, 251 F.3d 219 (2001), which invalidated a portion of a Vermont demonstration project in which Vermont provided a prescription drug benefit to certain populations where the costs to the State would be fully reimbursed by the amount owed by drug manufacturers under the Secretary's rebate agreement. *Id.* at 224 (holding that 42 U.S.C. 1396r-8(b)(1)(A) requires un-reimbursed "payments with state or federal funds appropriated for Medicaid expenditures"). A district court has rejected petitioner's challenge to the non-DEL component of Maine's demonstration project, holding that Maine's un-reimbursed two-percent contribution constitutes a "payment" under the federal Medicaid Act. *PhRMA* v. *Thompson*, 191 F. Supp. 2d 48, 62-63 (D.D.C. 2002), appeal pending, No. 02-5110 (D.C. Cir. argument scheduled Dec. 5, 2002).

scription drugs can have a serious impact on the health of low-income persons and that "[e]xpanded access to medically necessary drugs will make it much more likely that this category of individuals will be healthier and potentially able to remain not eligible for Medicaid." *Ibid.* The Secretary also determined that the program "would allow [CMS] to obtain valuable data regarding drug utilization patterns for these low-income individuals who previously did not have a prescription drug benefit." *Ibid.*

The Secretary has also approved similar Pharmacy Plus demonstration projects in Florida, Illinois, Maryland, South Carolina, and Wisconsin, that provide Medicaid prescription drug and primary care coordination benefits to low-income individuals, generally seniors with incomes less than 200% of the federal poverty level. As CMS has explained, those projects "will test how provision of a pharmacy benefit to a non-Medicaid covered population will affect Medicaid costs, utilization, and future eligibility trends," and may be budget-neutral by "reduc[ing] the costs the State incurs for State plan eligible groups through lesser service utilization, reduced period of Medicaid eligibility, and more effective pharmacy benefit management." http://cms.hhs.gov/medicaid/1115/rxfactsheet41202.pdf.[8]

For instance, Illinois explained in its demonstration project application to the Secretary that "every dollar spent on pharmaceutical coverage is associated with a significant reduction in hospital care expenditures." Illinois Dep't of Public Aid 1115 Demonstration Waiver Application at 1, 4 (July 31, 2001). Those "savings relate not only to the preventive nature of some pharmaceuticals, but also to the fact that inadequate coverage of this primary care benefit causes millions of low-income elderly to reduce their use of clinically essential medications." *Id.* at 1, 4-5. Illinois accordingly predicted that its demonstration project will, *inter alia*, "[r]educe the speed at which seniors 'spend down' and become entitled to all benefits available under the Medicaid program." *Id.* at 3.

[8] The Secretary has received applications for similar projects from Arkansas, Connecticut, Indiana, Maine, Massachusetts, and New Jersey.

Florida likewise explained in its application to the Secretary that, "[w]hile the demonstration includes individuals who are not currently eligible for Medicaid, this new population could become eligible for Medicaid through deterioration in their health status and reduced income due to high medical expenses." State of Florida, *Pharmacy Plus, A Demonstration Program Under Section 1115*, at 16 (June 6, 2002). Florida estimated that "approximately 5,800 aged individuals will be diverted each year from the Medicaid program" because a prescription drug benefit will "improve the value of primary care by preventing illness that otherwise would require hospital[ization] or institutionalization." *Id.* at 21. Florida further predicted that the drug benefit "will also relieve individuals of the financial burdens that are associated with pharmaceuticals, thereby allowing them to maintain current financial stability and become Medicaid eligible less quickly." *Id.* at 21-22; accord Letter from Wendy E. Warring, Comm'r Mass. Exec. Office of Health & Human Servs., to Melissa Harris, CMS (May 1, 2002), attaching Massachusetts Pharmacy 1115 Demonstration Waiver Request ("The cost reductions [under Medicaid] would be realized from a decrease in premature reliance on the Medicaid program due to avoidable deterioration in health conditions, reductions in utilization of community or institutional long-term care services, and delays in individual spend-downs into the Medicaid program.").

2. *The Secretary May Approve A State Plan Amendment That Would Impose A Prior Authorization Program Designed To Obtain Drug Discounts For Non-Medicaid Recipients If It Would Sufficiently Further Medicaid Objectives*

As discussed at pages 14-18, *supra*, the Medicaid program's drug rebate provisions permit States to implement a prior authorization program in order to secure prescription drug discounts for Medicaid recipients. States may also be able, consistent with the Medicaid program, to make drugs more affordable to certain non-Medicaid populations by subjecting drugs to prior authorization under Medicaid in order to encourage drug manufacturers to agree to offer prescription drug discounts for those populations.[9] The Secretary has not yet approved any such state initiatives.[10] The Secretary has determined, moreover, that any such initiatives would constitute a "['m]aterial change[] in State law, * * * policy, or in the State's operation of the Medicaid program'" and therefore would require an amendment to the state plan. 42 C.F.R. 430.12(c)(1)(ii). In light of that determination, the Secretary has advised State Medicaid Directors that any

[9] On July 31, 2002, the Senate passed Senate Bill No. S. 812, 107th Cong., 2d Sess., 148 Cong. Rec. S7651 (daily ed. July 31, 2002), which would amend Section 1396r-8 to provide that nothing in that provision prohibits a State from directly entering into a rebate agreement with a drug manufacturer nor from making prior authorization a condition of not participating in a rebate agreement in order to increase the affordability of outpatient prescription drugs for non-Medicaid eligible individuals.

[10] Contrary to petitioner's assertion in its brief in response to the United States' amicus brief filed at the certiorari stage (Supp. Br. 4 n.5), the Secretary did not approve an initiative by Michigan, which petitioner has challenged. That program requires drug manufacturers to extend supplemental drug rebates for drugs purchased by non-Medicaid individuals who are not eligible under Medicaid but fall below the poverty line, are elderly and fall near the poverty line, or are children with special diseases that are costly to treat. Mich. Opp. to Mot. for Prelim. Inj. at 10 n.5, *PhRMA* v. *Thompson*, *supra* (describing relevant non-Medicaid populations); note 4, *supra*.

State that wishes to establish a prior authorization program under the state plan in order "to secure drug benefits, rebates, or discounts for non-Medicaid populations" is expected to submit such a program for approval under the Secretary's regulations for approval of state plans and plan amendments. SMD Letter, *infra*, 48a; see 42 C.F.R. 430.10-430.18.[11] The Secretary has informed State Medicaid Directors that in submitting a plan amendment, "the State should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and objectives of the Medicaid program." SMD Letter, *infra*, 48a-49a.

For instance, as a result of the eligibility restrictions under Medicaid, many genuinely lower-income persons do not meet Medicaid's eligibility requirements. As of 1998, only 40% of those persons with incomes below the federal poverty level were covered by Medicaid. *2000 Green Book* 902. A prescription drug discount for non-Medicaid populations, made possible by encouraging manufacturers to give rebates, could significantly decrease the chance that such individuals will become Medicaid-eligible as either categorically or medically needy individuals, and thereby drain the State's scarce Medicaid resources. Upon an adequate showing, the Secretary could reasonably conclude that a proposed plan amendment that targeted a narrowly defined class of persons who have a low income but nonetheless are not eligible under Medicaid would sufficiently advance the interests of Medicaid program and its recipients "as a whole" to warrant approval. SMD Letter, *infra*, 49a. As the court below observed, "[w]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further

[11] Petitioner has not challenged the Maine Rx Program on the ground that it was not submitted to the Secretary for approval as an amendment to the State's Medicaid plan. There accordingly is no occasion in this case to consider whether petitioner would have a cause of action to challenge the Maine Rx Program on that ground.

into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible." Pet. App. 13; see also pp. 25-27, *supra*.

There is no reason in this case, however, for the Court to consider the scope of the Secretary's authority in this regard. As discussed above, the Maine Rx Program at issue in this case was adopted without the approval of the Secretary. That program, moreover, is not tailored to serve low-income populations. For that reason, the provision of the Maine Rx Program that imposes a prior authorization requirement under the State's Medicaid program on drug manufacturers that have not entered into a drug rebate agreement does not sufficiently advance a Medicaid-related goal.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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APPENDIX A

1. Section 1315, of Title 18, U.S.C., provides in relevant part:

§ 1315. Demonstration projects

(a) Waiver of State plan requirements; costs regarded as State plan expenditures; availability of appropriations

In the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of subchapter I, X, XIV, XVI, or XIX of this chapter, or part A or D of subchapter IV of this chapter, in a State or States—

(1) the Secretary may waive compliance with any of the requirements of section 302, 602, 654, 1202, 1352, 1382, or 1396a of this title, as the case may be, to the extent and for the period he finds necessary to enable such State or States to carry out such project, and

(2)(A) costs of such project which would not otherwise be included as expenditures under section 303, 655, 1203, 1353, 1383, or 1396b of this title, as the case may be, and which are not included as part of the costs of projects under section 1310 of this title, shall, to the extent and for the period prescribed by the Secretary, be regarded as expenditures under the State plan or plans approved under such subchapter, or for administration of such State plan or plans, as may be appropriate, and

(B) costs of such project which would not otherwise be a permissible use of funds under part A of subchapter IV of this chapter and which are not

included as part of the costs of projects under section 1310 of this title, shall to the extent and for the period prescribed by the Secretary, be regarded as a permissible use of funds under such part.

In addition, not to exceed $4,000,000 of the aggregate amount appropriated for payments to States under such subchapters for any fiscal year beginning after June 30, 1967, shall be available, under such terms and conditions as the Secretary may establish, for payments to States to cover so much of the cost of such projects as is not covered by payments under such subchapters and is not included as part of the cost of projects for purposes of section 1310 of this title.

* * * * *

2. Section 1396a of Title 42, U.S.C., provides in relevant part:

§ 1396a. State plans for medical assistance

(a) Contents

A State plan for medical assistance must—

* * * * *

(19) provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients;

* * * * *

(30)(A) provide such methods and procedures relating to the utilization of, and the payment for, care

and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area;

* * * * *

(54) in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1396r-8(k) of this title), comply with the applicable requirements of section 1396r-8 of this title;

* * * * *

3. Section 1396r-8 provides:

§ 1396r-8. Payment for covered outpatient drugs

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) of this section with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of para-

graph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) Effective date

Paragraph (1) shall first apply to drugs dispensed under this subchapter on or after January 1, 1991.

(3) Authorizing payment for drugs not covered under rebate agreements

Paragraph (1), and section 1396b(i)(10)(A) of this title, shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance

with a prior authorization program described in subsection (d) of this section, or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) Effect on existing agreements

In the case of a rebate agreement in effect between a State and a manufacturer on November 5, 1990, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this subchapter. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on November 5, 1990, provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) Limitation on prices of drugs purchased by covered entities

(A) Agreement with Secretary

A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 256b of this title with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992.

(B) "Covered entity" defined

In this subsection, the term "covered entity" means an entity described in section 256b(a)(4) of this title.

(C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates

If the Secretary does not establish a mechanism under section 256b(a)(5)(A) of this title within 12 months of November 4, 1992, the following requirements shall apply:

(i) Entities

Each covered entity shall inform the single State agency under section 1396a(a)(5) of this title when it is seeking reimbursement from the State plan for medical assistance described in section 1396d(a)(12) of this title with respect to a unit of any covered outpatient drug which is subject to an agreement under section 256b(a) of this title.

(ii) State agency

Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 256b of this title, and not submit to any manufacturer a claim for a rebate payment under subsection (b) of this section with respect to such a drug.

(D) Effect of subsequent amendments

In determining whether an agreement under subparagraph (A) meets the requirements of section 256b of this title, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(E) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 256b of this title (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(6) Requirements relating to master agreements for drugs procured by Department of Veterans Affairs and certain other Federal agencies

(A) In general

A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of title 38, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) Effect of subsequent amendments

In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(C) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(b) Terms of rebate agreement

(1) Periodic rebates

(A) In general

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) of this section for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) of this section or an agreement described in subsection (a)(4) of this section) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title.

(2) State provision of information

(A) State responsibility

Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total

number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

(B) Audits

A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price information

(A) In general

Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1) of this section) and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B) of this section) for covered outpatient drugs for the rebate period under the agreement, and

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1) of this section) as of October 1,

1990[1] for each of the manufacturer's covered outpatient drugs.

(B) Verification surveys of average manufacturer price

The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1320a-7a of this title (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(C) Penalties

(i) Failure to provide timely information

In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in

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[1] So in original. Probably should be followed by a comma.

which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) False information

Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(D) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) of this section is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler,

prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section,

(ii) to permit the Comptroller General to review the information provided, and

(iii) to permit the Director of the Congressional Budget Office to review the information provided.

(4) Length of agreement

(A) In general

A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) Termination

(i) By the Secretary

The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) By a manufacturer

A manufacturer may terminate a rebate agreement under this section for any reason. Any such

termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) Effectiveness of termination

Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) Notice to States

In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) Application to terminations of other agreements

The provisions of this subparagraph shall apply to the terminations of agreements described in section 256b(a)(1) of this title and master agreements described in section 8126(a) of title 38.

(C) Delay before reentry

In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) Determination of amount of rebate

(1) Basic rebate for single source drugs and innovator multiple source drugs

(A) In general

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8) of this section) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) Range of rebates required

(i) Minimum rebate percentage

For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent; and

(V) after December 31, 1995, is 15.1 percent.

(ii) Temporary limitation on maximum rebate amount

In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(C) "Best price" defined

For purposes of this section—

(i) In general

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section;

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program; and

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.

(ii) Special rules

The term "best price"—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and

(III) shall not take into account prices that are merely nominal in amount.

(2) Additional rebate for single source and innovator multiple source drugs

(A) In general

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) Treatment of subsequently approved drugs

In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

(3) Rebate for other drugs

(A) In general

The amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) Applicable percentage defined

For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning—

(i) before January 1, 1994, is 10 percent, and

(ii) after December 31, 1993, is 11 percent.

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) of this section or in effect pursuant to subsection (a)(4) of this section; or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(3) Update of drug listings

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3) of this section).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6) of this section), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written

explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the

dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

(e) Treatment of pharmacy reimbursement limits

(1) In general

During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this sub chapter or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph(2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) Special rule

If a State is not in compliance with the regulations described in paragraph(1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) Effect on State maximum allowable cost limitations

This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

[(4)][2] Establishment of upper payment limits

HCFA shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

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[2] See 1993 Amendment note below.

(f) Repealed and redesignated

(1) Repealed. Pub.L. 103-66, title XIII, § 13602(a)(1), Aug. 10, 1993, 107 Stat. 613

(2) Redesignated (e)[(4)]

(g) Drug use review

(1) In general

(A) In order to meet the requirement of section 1396b(i)(10)(B) of this title, a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information;

(III) the DRUGDEX Information System; and

(IV) American Medical Association Drug Evaluations; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1396b of this title, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1396r of this title, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) Description of program

Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) Prospective drug review

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serius interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this subchapter by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent

with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this subchapter:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this subchapter or caregiver of such individual refuses such consultation.

(B) Retrospective drug use review

The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b(r) of this title) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

(C) Application of standards

The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection[3] (1)(B)as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) Educational program

The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

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[3] So in original. Probably should be "paragraph."

(3) State drug use review board

(A) Establishment

Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) Membership

The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 * * *[4] licensed and actively practicing pharmacists.

[4] So in original.

(C) Activities

The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section[5] (2)(B).

(ii) Application of standards as defined in section[5] (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers

[5] So in original. Probably should be "paragraph."

and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) Annual report

Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) Electronic claims management

(1) In general

In accordance with chapter 35 of title 44 (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this subchapter, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) Encouragement

In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1396b(a)(3)(A)(i) of this title (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's

request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) Omitted

(j) Exemption of organized health care settings

(1) Covered outpatient drugs dispensed by health maintenance organizations, including medicaid managed care organizations that contract under section 1396b(m) of this title, are not subject to the requirements of this section.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c) of this section.

(k) Definitions

In this section—

(1) Average manufacturer price

The term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price

paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

(2) Covered outpatient drug

Subject to the exceptions in paragraph(3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 [21 U.S.C. 355] or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act [21 U.S.C. 355(j)];

(ii)(I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C. 331, 332(a), 334(a)]

to enforce section 502(f) or 505(a) of such Act [21 U.S.C. 352(f), 355(a)]; or

(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 262 of this title, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. S 356].

(3) Limiting definition

The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration

or a drug or biological[6] used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C) of this section) for such drug, biological product, or insulin.

(4) Nonprescription drugs

If a State plan for medical assistance under this subchapter includes coverage of prescribed drugs as described in section 1396d(a)(12) of this title and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) Manufacturer

The term "manufacturer" means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

[6] So in original. Probably should be "biological product."

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Medically accepted indication

The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug

(A) Defined

(i) Multiple source drug

The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which—

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the State during the period.

(ii) Innovator multiple source drug

The term "innovator multiple source drug" means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) Noninnovator multiple source drug

The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) Single source drug

The term "single source drug" means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) Exception

Subparagraph (A)(1)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(1)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) Definitions

For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

(8) Rebate period

The term "rebate period" means, with respect to an agreement under subsection (a) of this section, a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) State agency

The term "State agency" means the agency designated under section 1396a(a)(5) of this title to administer or supervise the administration of the State plan for medical assistance.

APPENDIX B

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

September 18, 2002

Dear State Medicaid Director:

This letter is to clarify issues related to supplemental drug rebate agreements and prior authorization of Medicaid covered outpatient drugs. A number of States have sought CMS approval of supplemental drug rebate agreements between a State and drug manufacturers with respect to Medicaid covered outpatient prescription drugs. Some of these States subject covered outpatient drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients.

Medicaid Supplemental Drug Rebate Agreements

States may enter separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth in the Secretary's national rebate agreement with drug manufacturers, which is published at 56 F.R. 7049 (1991). The drug rebate statute, at section 1927(a)(1) of the Social Security Act (Act), provides that "the Secre-

tary may authorize a State to enter directly into agreements with a manufacturer." Also, section 1927(a)(4) of the Act provides that any drug rebate agreement between a State and drug manufacturers and in effect on November 5, 1990, may constitute a rebate agreement in compliance with the statute if CMS determines that any such agreement "provides for rebates that are at least as large as the rebates otherwise required under this section." CMS accordingly believes that Congress intended that States that seek CMS approval under section 1927(a)(1) to enter directly into agreements with manufacturers must ensure that any such agreement will achieve drug rebates that are at least equal to the rebates set forth in the Secretary's rebate agreements with manufacturers.

We remind States that supplemental drug rebates must be "considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance" as required by section 1927(b)(1)(B) of the Act.

Prior Authorization Requirements Related to Supplemental Rebate Agreements

States may subject covered outpatient prescription drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients. Section 1927(d)(1)(A) of the Act permits States to subject any covered outpatient drug to a requirement of prior authorization as long as the State complies with the requirements set forth in section 1927(d)(5). A prior authorization program used to negotiate drug discounts for the Medicaid program is consistent with those provisions as well as the paramount purpose of the drug rebate provisions which is to

reduce the costs to the Medicaid program for prescription drugs.

A prior authorization program does not need to comply with the requirements for restrictive formularies. The formulary provisions of section 1927(d)(4) were added to the drug rebate provisions in 1993 to give States additional authority to implement restrictive formularies. Congress passed paragraph (d)(4) expressly stating that "[a] prior authorization program established by a State under [section 1927(d)(5)] is not a formulary subject to the requirements of this paragraph."* Furthermore, since concerns related to drug use, monitoring, waste, fraud or abuse are separately and independently addressed by the procedures authorized by sections 1927(d)(6) and 1927(g), a prior authorization program need not be limited to those concerns. The Act affords States broad authority and flexibility to implement a prior authorization program in order to secure cost savings for the Medicaid program.

The operation of a prior authorization program used to negotiate drug discounts for the Medicaid population is a significant component of a State plan. We would therefore expect that a State that does not currently have an approved prior authorization State plan amendment, and that seeks to undertake such a program, would submit to CMS for review a State plan amendment incorporating the program's prior authorization requirements, while simultaneously seeking

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* Of course, the formulary provisions of section 1927(d)(4) continue to apply if a State chooses to make judgments about the therapeutic advantages of a drug excluded from a formulary, and the State plan must permit coverage of any such drug pursuant to a prior authorization program that complies with section 1927(d)(5).

CMS's authorization for its proposed separate or supplemental rebate agreement. A State that has an approved State plan amendment governing prior authorization requirements, but which seeks for the first time to use its prior authorization authority to negotiate drug discounts for the Medicaid program, must amend its State plan to refer to the separate or supplemental rebate agreement and submit its proposed rebate agreement for CMS authorization.

Non-Medicaid Supplemental Rebates and Medicaid Prior Authorization

A number of States secure prescription drug benefits, rebates, or discounts for *non-Medicaid* populations by linking such benefits to a Medicaid prior authorization program. The Act does not preclude States from negotiating prices, including manufacturer discounts and rebates for non-Medicaid drug purchases. However, the establishment of a prior authorization program for Medicaid covered drugs to secure drug benefits, rebates, or discounts for non-Medicaid populations is a significant component of a State plan and we would therefore expect that a State would submit such a program for CMS review under the State plan process. Similarly, the use of any pre-existing prior authorization program to secure drug benefits, rebates, or discounts for non-Medicaid populations would constitute a "[m]aterial change[] in State law, . . . policy, or in the State's operation of the Medicaid program" and we would therefore expect that a State would submit a plan amendment to CMS for review. (See section 430.12(c)(1)(ii) of the regulations.) In submitting such a State plan amendment, the State should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and

objectives of the Medicaid program. A State could make such a demonstration by submitting appropriate evidence that its prior authorization requirement is designed to increase the efficiency and economy of the Medicaid program. A State could demonstrate that its prior authorization requirement furthers Medicaid goals and objectives by submitting appropriate evidence that the requirement sufficiently benefits the Medicaid population as a whole by making available to financially needy individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible.

If you have any questions regarding CMS policy relating to supplemental drug rebate agreements or prior authorization programs, please direct them to Larry Reed at (410) 786-3325 or Deirdre Duzor at (410) 786-4626.

Sincerely,

Dennis G. Smith
Director

cc:

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(10)

No. 01-188

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, Commissioner, Maine Department of Human Services; and G. STEVEN ROWE, Attorney General of Maine,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION, ALLIED EDUCATIONAL FOUNDATION, KIDNEY CANCER ASSOCIATION, THE SENIORS COALITION, THE 60 PLUS ASSOCIATION, and THE INTERNATIONAL PATIENT ADVOCACY ASSOC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTIONS PRESENTED

1. Does the federal Medicaid statute, 42 U.S.C. § 1396, *et seq.*, allow a state to use authority under that statute to compel drug manufacturers to subsidize price discounts on prescription drugs for non-Medicaid populations?

2. May a State circumvent the Commerce Clause prohibition against regulating or taxing wholly out-of-state transactions by requiring an out-of-state manufacturer, which sells its products to wholesalers outside the State, to pay the State each time one of its products is subsequently sold by a retailer within the State?

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BRIEF OF WASHINGTON LEGAL FOUNDATION, ALLIED EDUCATIONAL FOUNDATION, KIDNEY CANCER ASSOCIATION, THE SENIORS COALITION, THE 60 PLUS ASSOCIATION, AND INTERNATIONAL PATIENT ADVOCACY ASSOC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF)[1] is a non-profit public interest law and policy center with supporters in all 50 states, including many in Maine. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. To that end, WLF has appeared before numerous federal and state courts in cases raising issues arising under the dormant Commerce Clause. *See, e.g., National Foreign Trade Council v. Natsios,* 181 F.3d 38 (1st Cir. 1999), *aff'd,* 530 U.S. 363 (2000). WLF recently successfully challenged the constitutionality of Food and Drug Administration restrictions on commercial speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000).

The Allied Educational Foundation (AEF) is a non-profit charitable and educational foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study,

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, contributed monetarily to the preparation and submission of this brief.

such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

The Kidney Cancer Association is a patient and survivor-led voluntary health agency pursuing the goal of a world without kidney cancer through research, education, and advocacy.

The Seniors Coalition (TSC) is a non-profit, non-partisan education and issue advocacy organization that represents the interests and concerns of America's senior citizens at both the state and local levels. TSC's mission is to give America's seniors a real voice in government to enact public policies that promote and protect their quality of life and economic security. Founded in 1989, TSC has grown to nearly 4 million members; its advocacy includes a wide range of issues important to seniors, including Social Security, Medicare, long-term care, generic drug access, and tax reform.

The 60 Plus Association is a Virginia-based seniors' advocacy group devoted to the free market, free enterprise system. 60 Plus is opposed to price controls on prescription drugs because: (1) they stifle pharmaceutical research leading to the medical miracles enabling seniors to live longer and better and stay out of hospitals; and (2) they result in shortages, as evidenced by the shortcomings of the Canadian health care system.

The International Patient Advocacy Association (IPAA) is a non-profit organization based in Bellevue, Washington. IPAA's mission is to work closely with patients, physicians, industry, researchers, and legislators to provide legal and patient advocacy, free of charge.

Amici are concerned that the Maine Rx Program, if allowed to take effect, will have long-term adverse effects on health care in this country. By interfering with the free market in pharmaceutical sales, the Program threatens to discourage research and development of new, life-saving drugs and to Balkanize what is now an efficient national market.

Amici also filed a brief in this case in support of the petition for a writ of certiorari, and when it was before the appeals court. *Amici* are filing this brief with the consent of all parties. The written consents are on file with the Clerk of the Court.

STATEMENT OF THE CASE

In the interests of brevity, WLF hereby adopts by reference the Statement of the Case contained in Petitioner's brief.

In brief, the Pharmaceutical Research and Manufacturers of America ("PhRMA") challenges a Maine law that requires drug manufacturers to subsidize retail drug discounts to Maine residents under a new program called the "Maine Rx Program." Payment of the subsidies is (from a practical standpoint) mandatory, because the State of Maine administers the federal Medicaid program within the State (a program in which all major drug manufacturers participate), and the Maine Rx Program prescribes severe retaliation in connection with Medicaid against any manufacturer that refuses to pay the mandated subsidy. *See* Petition Appendix ("Pet. App.") 70-71.

The Maine RX Program was adopted by the state legislature in May 2000. The law, entitled "An Act to Establish Fairer Pricing for Prescription Drugs" (the "Act"), 2000 Me. Legis. Ch. 786 (S.P. 1026), is codified at 22 M.R.S.A. § 2681. The Act provides that drug manufacturers "shall enter into a rebate agreement" with the Maine Department of Human Services (the "Department") and that the agreement "must require" manufacturers to "make rebate payments to the State each calendar quarter or according to a schedule established by the department." 22 M.R.S.A. § 2681(3). The Act further requires the Department to use "best efforts" to establish rebates at a level equal to or greater than discounts obtained by the federal government in connection with its bulk purchases of prescription drugs. 22 M.R.S.A. § 2681(4). The Act further provides that pharmacists in Maine are to sell prescription drugs to Maine residents at substantially discounted prices and that money collected by the State from drug manufacturers under the Maine Rx Program is to be paid to the pharmacists in order to reimburse them for those discounts. 22 M.R.S.A. §§ 2681(5), (6).

The subsidies are required of all drug manufacturers whose products are sold in Maine, even though no drug manufacturers are based in Maine and even though very few of them sell their products to Maine wholesalers. Rather, virtually all prescription drugs that end up in Maine are sold to wholesalers or distributors in transactions that occur outside the State; the wholesalers and distributors make their own arrangements for shipment into Maine. Pet. App. 60. Moreover, as the district court recognized, the rebate program results in a reduction in the wholesale price obtained by manufacturers for each drug that is later sold in Maine, because the amount of a manufacturer's rebate is determined

by the quantity of that manufacturer's products sold in Maine. *Id.* at 66.

PhRMA filed suit against the Maine Rx Program in U.S. District Court for the District of Maine. The Complaint alleged that the Program violated the Commerce Clause of the U.S. Constitution by attempting to regulate transactions occurring outside of Maine, and violated the Supremacy Clause by requiring Maine to administer the Medicaid program in a manner that conflicts with federal law.

On October 26, 2000, the district court granted PhRMA's motion for a preliminary injunction against any efforts by Maine to enforce the payment of rebates under the Program. Pet. App. 57-72. Initially, the court rejected Maine's argument that the Maine Rx Program entailed nothing more than the exercise of power derived from Maine's role as a participant in the prescription drug market, and thus that the Program should be exempt from Commerce Clause scrutiny under the "market participation" exception. The court said that that exception does not immunize State efforts to leverage power derived from one market in which it participates (in this case, the purchase of drugs under the Medicaid program) in order to regulate a market in which it does not participate (in this case, the market for prescription drugs purchased outside of Medicaid). *Id.* at 61-64.

The court went on to find that the Program violated the Commerce Clause because it attempted to regulate transactions taking place solely outside the State. *Id.* at 64-66. "Maine may have power over what pharmacies later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the price paid in earlier transactions in other states." *Id.* at 65. The court

held that the Program was invalid without regard to whether the Program could be said to discriminate against out-of-staters in favor of in-staters. *Id.* at 66.

The court also held that the Program was invalid under the Supremacy Clause because it was impliedly preempted by federal Medicaid law. *Id.* at 66-70. The court found that the Program stood "as an obstacle to the accomplishment and execution of the Congressional objectives of federal Medicaid," because it made it more difficult for certain drugs to be prescribed to Medicaid recipients. *Id.* at 68.

Having found that PhRMA was "overwhelming[ly]" likely to prevail on the merits and that the other relevant factors also favored PhRMA, the court granted a preliminary injunction against enforcement of the Program's rebate scheme. *Id.* at 72.

The U.S. Court of Appeals for the First Circuit reversed and vacated the preliminary injunction. *Id.* at 1-53. The appeals court initially determined that the Program was not preempted by federal law, finding "no conflict between the Maine Act and Medicaid's structure and purpose." *Id.* at 11. While noting that the Program threatens imposition of a "prior authorization" requirement on manufacturers that do not participate in the Act's price control program, the court held that the Medicaid statute does not concern itself with a State's motivation in choosing to impose such a requirement -- and thus that Maine's use of its "prior authorization" power as a club to ensure manufacturer participation does not conflict with any purpose of the Medicaid law. *Id.* at 12-13. The court said that the Program actually "furthers Medicaid's aim of providing medical services to those" otherwise unable

to meet the costs of necessary medical services but who are not poor enough to qualify for Medicaid. *Id.* at 13.

The appeals court also held that the Program did not violate the Commerce Clause. *Id.* at 17-27. As did the district court, the appeals court rejected Maine's argument that it was exempt from Commerce Clause restraints by virtue of its status as a "market participant." *Id.* at 20. The court nonetheless rejected PhRMA's Commerce Clause challenge, finding that "the Maine Act does not impose direct controls on a transaction that occurs wholly out-of-state," *Id.* at 23. The court reasoned, "Simply because the manufacturers' profits might be negatively affected by the Maine Act . . . does not necessarily mean that the Maine Act is regulating those profits." *Id.* The court held that whatever burdens the Program imposed on interstate commerce were not "clearly excessive" in relation to the benefits derived by Maine. *Id.* at 25-27.

On June 13, 2001, the First Circuit issued an order stating that no action could be taken on PhRMA's petition for rehearing *en banc*. Pet. App. 54-55. The court explained that -- except for Judge Torruella, who voted in favor of rehearing *en banc* -- all of the First Circuit judges in regular active service had recused themselves from the case. *Id.*

SUMMARY OF ARGUMENT

The Maine Rx Program threatens to impose prior authorization requirements on Medicaid coverage for any drug manufactured by a company that does not agree to charge substantially reduced prices to uninsured individuals. By doing so, Maine no doubt is providing a substantial cost savings to its non-Medicaid population. But at the same time,

the Program jeopardizes the health of Medicaid recipients by potentially denying them access to optimal medical care. The Medicaid statutes are intended to ensure that even those with very low incomes have access to a high level of medical care. Accordingly, the Maine Rx Program is preempted by federal law; such preemption is mandated whenever, as here, the challenged State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

The Maine RX Program should be enjoined for the additional reason that it violates the Commerce Clause. Despite Maine's assertions to the contrary, the Program can only be viewed as an effort by the State to impose price controls on wholesale drug transactions that take place entirely outside Maine. Such extraterritorial applications of State law are *per se* invalid under the Commerce Clause. Nor may Maine seek protection from the Commerce Clause by invoking the "market participant" exception, in the absence of evidence that Maine's operation of the Program was more akin to that of a market participant than to that of a government regulator.

ARGUMENT

I. MAINE'S USE OF ITS PRIOR AUTHORIZATION AUTHORITY TO AID NON-MEDICAID POPULATIONS CONFLICTS WITH, AND THUS IS PREEMPTED BY, FEDERAL MEDICAID LAW

Although the Maine Rx Program is independent of the State's administration of Medicaid, the Program uses a provision of Medicaid as a club to ensure manufacturer participation in its rebate program, the "prior authorization"

provision.[2] When subjected to prior authorization, a drug may not be dispensed to a Medicaid beneficiary without the approval of the State Medicaid administrator. The Maine Rx Program threatens that all of a manufacturer's drugs will be subject to Medicaid prior authorization if the manufacturer fails to participate in the rebate program. Because all pharmaceutical manufacturers derive significant income from Medicaid and because it is well accepted that any company whose drugs are subjected to Medicaid prior authorization will suffer significant sales loss, manufacturers are, for all intents and purposes, forced to participate in the Maine Rx Program. As the district court found, the Maine Rx Program cannot realistically be deemed "voluntary." Pet. App. 70-71.

In other words, Maine is using the authority it possesses by virtue of its role as Medicaid administrator to aid individuals who are not eligible to participate in Medicaid. *Amici* believe it plain that Maine's use of its authority in that manner conflicts with federal law and thus is preempted by it. While no provision of the Medicaid law expressly forbids what Maine has done, the Maine Rx Program is impliedly preempted by federal law because it is inconsistent with Medicaid's objectives.

State law is impliedly preempted if: (1) it actually conflicts with federal law; or (2) federal law so thoroughly occupies a legislative field "as to make reasonable the inference that Congress left no room for the States to supplement it." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citations omitted). State law "actually

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[2] *See* 42 U.S.C. § 1396r-8(d)(1), (5), which authorize states to impose prior authorization requirements for prescriptions paid by Medicaid, subject to certain procedural safeguards.

conflicts" with federal law "*either* because compliance with both federal law and state regulations is a physical impossibility, *or* because the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *California Fed. Sav. and Loan Ass'n v. Guerra,* 479 U.S. 272, 281 (1987) (emphasis added and internal quotations omitted).

As the district court accurately noted:

> The purposes of the federal Medicaid program are straightforward: to provide medical services, including prescription drugs, 42 C.F.R. §§ 456.702-3 (West 2000), to those with medical needs who qualify under Medicaid's eligibility standards. 42 U.S.C.A. § 1396 (West 1992); *Mayburg v. Secretary of Health & Human Servs.*, 740 F.2d 100, 103 (1st Cir. 1983) (noting the general principle that the Social Security Act should be broadly construed "to carry our Congress's intent to provide medical expense coverage for all qualifying individuals"). To that end, Congress has demanded that any state restriction on drug distribution "provide such safeguards as may be necessary to assure that care and services . . . will be provided *in a manner consistent with the best interest of Medicaid's requirements.*" 42 U.S.C. § 1396c(a)(19) (West 1992) (emphasis added). Nowhere has Congress suggested that the federal Medicaid program can be used to further the interests of *non*-Medicaid recipients.

Pet. App. 68.

While conceding that the Maine Rx Program did not benefit anyone eligible to receive Medicaid benefits, the First

Circuit insisted that -- in determining whether state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" and thus is preempted -- the absence of a "Medicaid purpose" in the Maine Rx Program was not fatal to the program:

> [W]e are not convinced that the Medicaid statute is concerned with the motivation behind imposing prior authorization, as long as the 24-hour response and the 72-hour drug-supply requirements, 42 U.S.C. § 1396r-8(d)(5), are satisfied. Thus, even if the district court's conclusion that "Maine can point to no Medicaid purpose in this new prior authorization requirement" is true, it does not necessarily mean that the prior authorization scheme *conflicts* with the objectives of the Medicaid program. We so no basis for inflicting the "strong medicine" of preemption on a state statute that, in the absence of an actual conflict, merely fails to directly advance the purpose of the federal program.

Pet. App. 12-13.

The First Circuit's analysis is faulty, on several grounds. First, the appeals court erred in adopting at the outset a strong presumption that State law was not preempted. The court dubbed preemption of a state law "strong medicine" that is "not casually to be dispensed." *Id.* at 10 (quoting *Grant's Dairy-Me., LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res.*, 232 F.3d 8, 18 (1st Cir. 2000). The court added:

> This [presumption against preemption] is especially true when the federal statute creates a program, such as Medicaid, that utilizes "cooperative federalism":

> "Where coordinated state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one."

Id. (quoting *Wash., Dep't of Soc. & Health Servs. v. Bowen,* 815 F.2d 549, 557 (9th Cir. 1987)).

There is absolutely no support in this Court's case law for the appeals court's assertion that there is a particularly strong presumption against preemption in cases involving "cooperative federalism." To the contrary, "Pre-emption fundamentally is a question of congressional intent . . .," *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990), and there is no reason to assume that Congress is less likely to have intended to preempt State law in cases involving "cooperative federalism" than in other types of cases. Because States do not have any history of administering the Medicaid program without federal government involvement -- indeed, Medicaid is wholly a creature of federal law -- preemption of State laws in that area does not raise any federalism concerns and thus there is little reason to presume that Congress did not intend to preempt State laws that "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See Buckman Co. v. Plaintiffs' Legal Committee,* 121 S. Ct. 1012, 1017 (2001) (presumption against preemption is inapplicable in cases in which federalism concerns are not implicated). Accordingly, the appeals court erred in looking beyond the four corners of the Medicaid statute in determining whether the Maine Rx Program stands as an obstacle to the accomplishment of Congress's purposes.

Second, the appeals court erred factually in asserting that "the Maine Rx Program furthers Medicaid's aim of providing medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical services,' 42 U.S.C. § 196, even if the individuals covered by the Maine Rx Program are not poor enough to qualify for Medicaid." Pet. App. 13. To the contrary, the Program includes no means test, and thus *any* State resident who does not have health insurance coverage is eligible to participate. There is a nonfrivolous argument that low-income individuals who are not quite poor enough to qualify for Medicaid nonetheless are included within the broad class of individuals whom Congress intended to benefit in adopting the Medicaid program. But in the absence of a provision limiting participation to lower-income individuals, the Program cannot plausibly be deemed one that is designed to benefit the (broadly defined) intended beneficiaries of Medicaid.

Third, the Program threatens to impose real hardship on Medicaid recipients within Maine. The Program provides that prior authorization requirements will be imposed on all the products of a manufacturer that refuses to pay rebates. Me. Rev. Stat. Ann. tit. 22, § 2681(7). The record evidence is overwhelming that sales fall for all drugs placed on the prior authorization list, and that patients find it increasingly difficult to obtain their prescription drug of choice once that drug is placed on the list. Pressuring patients and their physicians to turn to lower-cost drugs (manufactured by companies willing to pay rebates) may result in lower short-term medical expenditures for a State, but Medicaid recipients inevitably suffer when they are (effectively) denied access to the drug they and their physician would have preferred. The Medicaid statutes include numerous

provisions to ensure that, when such denials occur, they are based on sound medical judgments. *See, e.g.*, 42 U.S.C. § 1396r-8(d)(2) (allowing States to deny Medicaid coverage for certain categories of non-essential drugs, such as drugs used for cosmetic purposes). Permitting a State to deny coverage for a drug that a physician wishes to prescribe for her Medicaid patients, solely because the drug manufacturer refuses to provide discount prices to wealthy State residents who lack insurance coverage, is wholly inconsistent with Congress's declared purpose of providing quality medical care to Medicaid-eligible individuals.

Indeed, the federal government, in the brief it filed at the petition stage of this case, stated as much. While arguing that Court review of the issues raised was premature, the United States stated unequivocally:

> Congress . . . has authorized States under certain conditions to impose prior authorization requirements on otherwise covered outpatient drugs. 42 U.S.C. 1396r-8(a) (1994 & Supp. V 1999); 42 U.S.C. 1396r-8(d)(5). Congress enacted those provisions so that States "would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." H.R. Rep. No. 881, 101 Cong., 2d Sess. 98 (1990). Congress assuredly did not intend that a State would use a requirement of prior authorization for the prescription of drugs for Medicaid beneficiaries in a manner that would burden the ability of Medicaid recipients to receive covered drugs without serving *some* purpose related to Medicaid.

Brief for United States at 11.

In sum, the Maine Rx Program stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the Medicaid statute and thus is impliedly preempted.

II. THE MAINE RX PROGRAM VIOLATES THE COMMERCE CLAUSE

The Maine RX Program should be enjoined for the additional reason that its extraterritorial regulation of commerce violates the Commerce Clause. As did the First Circuit, the Court should reject Maine's argument that the "market participant" exception exempts the Program from Commerce Clause scrutiny.

A. The Program Is Not Exempted from Commerce Clause Scrutiny by the Market Participant Exception

Maine argued in the appeals court -- and may well choose to renew the argument here -- that regardless how much the Maine Rx Program burdens interstate commerce, the Program should be exempt from dormant Commerce Clause scrutiny because it falls within the "market participant" exception. Maine Court of Appeals Br. 30-35. That argument was rejected by the appeals court and continues to be without merit.

Under the "market participant" exception, a State or local government is not subject to dormant Commerce Clause limitations when its actions are not distinctively governmental in nature but rather it is acting in the role of a market

participant. *Camps Newfound/Owatonna, Inc. v. Town of Harrison,* 520 U.S. 564, 592 (1997). Thus, for example, a State that decides to pay a bounty for junked cars (as a means of encouraging the recycling of scrap metal) may show favoritism to in-state scrap metal processors without risking dormant Commerce Clause scrutiny. *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794 (1976). Similarly, a State that elects to operate a cement factory is not subject to dormant Commerce Clause constraints when it limits it sales to in-state customers. *Reeves, Inc. v. Stake,* 447 U.S. 429 (1980). Nor does the dormant Commerce Clause constrain a city engaged in the building trade that wishes to mandate that its contractors employ city residents. *White v. Massachusetts Council of Construction Employers, Inc.*, 460 U.S. 204 (1983).

The Court nonetheless has made clear that a State or local government may not rely on the market participant doctrine where it has used its leverage in a market in which it is a participant to impose burdens on commerce outside of that market. As the Court has explained:

> [T]he doctrine is not *carte blanche* to impose any conditions that the State has the economic power to dictate, and does not validate any requirement merely because the State imposes it upon someone with whom it is in contractual privity. . . . The limit of the market participant doctrine must be that it allows a State to impose burdens on commerce within the market in which it is a participant but allows it to go no further. The State may not impose conditions, whether by statute, regulation, or contract, that have a substantial regulatory effect outside of that particular market.

South-Central Timber Development, Inc. v. Wunnicke, 467 U.S. 82, 97 (1984) (plurality). The *Wunnicke* plurality determined that the market participant exception was inapplicable to Alaska's efforts to require those to whom it sold lumber to process the lumber within the State before shipping it elsewhere. *Id.* at 98. The plurality explained that the exception was inapplicable because Alaska was attempting to use its leverage in the market in which it was a participant (the timber sales market) "to exert a regulatory effect in the processing market, in which it is not a participant." *Id.*

There can be little doubt that the Maine Rx Program does not fit within the terms of the market participant exception. The Program -- an effort to regulate the price of all prescription drugs sold within the State -- is not the type of activity commonly thought of as proprietary in nature but rather is an example of "a State's acting in its distinctive governmental capacity," activity that the Supreme Court has repeatedly stated "is subject to the limitations of the negative Commerce Clause." *Camps Newfound/Owatonna*, 520 U.S. at 592.

Moreover, the market participant doctrine is wholly inapplicable when, as here, the State has played no role in creating the commerce which is alleged to have been improperly burdened. As Justice Stevens explained in *Alexandria Scrap*:

> It is important to differentiate between commerce which flourishes in a free market and commerce which owes its existence to a state subsidy program. Our cases finding that a state regulation constitutes an impermissible burden on interstate commerce all dealt with restrictions that adversely affected the operation of

> a free market. This case is unique because the commerce which Maryland has "burdened" is commerce which would not exist if Maryland had not decided to subsidize a portion of the automobile scrap-processing business.

Alexandria Scrap, 426 U.S. at 815 (Stevens, J., concurring). The market for prescription drug sales has existed in Maine for many years and will continue to exist regardless whether the Maine Rx Program ever takes effect. Accordingly, Maine may not invoke the market participant exception based on its alleged "participation" in a market which it played no role in creating.

Even conceding for the sake of argument that Maine is a "participant" in the Medicaid prescription drug market, it may not seek shelter in the market participant exception for its use of leverage in that market to regulate the sale of prescription drugs to residents ineligible for Medicaid. As the *Wunnicke* plurality explained, the market participant doctrine does not immunize a State that uses its leverage in a market in which it participates "to exert a regulatory effect" in a market in which it is not a participant. *Wunnicke,* 467 U.S. at 98 (plurality). If the doctrine were not "relatively narrowly defined" in this manner, it would have "the potential of swallowing up" dormant Commerce Clause limitation on a State's power to burden interstate commerce. *Id.*

In arguing for a contrary rule, Maine's reliance on *White* is misplaced. Maine argued that the Court invoked the market participant exception in *White* even though the City of Boston used its leverage in the market in which it participated (construction) to impose requirements (the hiring of city

residents) on its construction contractors in a market in which it was not a direct participant (the market for construction labor). Maine Br. 32. But *White* expressly disavowed Maine's characterization of the facts of that case; rather, the Court said that Boston was "a major participant" in the construction labor market. *White,* 460 U.S. at 211 n.7. The Court explained, "Everyone affected by the order [that at least 50% of those employed to work on the city's construction projects be city residents] is, in a substantial if informal sense, `working for the city.'" *Id.*

Inexplicably, Maine sought to turn *White*'s "in a substantial but informal sense" language to its own advantage. Maine argued:

> Here, all the prescription drugs consumed through the Maine Rx Program and Medicaid are "in a substantial but informal sense" for the benefit of the same population -- Maine residents without private insurance. Maine Rx beneficiaries will acquire the same prescription drugs, produced by the same manufacturers and sold by the same pharmacists, as their fellow residents on Medicaid. That Maine does not purchase the drugs in the Maine RX program is no more significant than the fact that Boston did not hire the laborers in *White*.

Maine Court of Appeals Br. 34. Maine's analogy to *White* makes absolutely no sense. *White* turned on the fact that the group for whose benefit Boston had acted (Boston residents hired to work on the city's construction contracts) could in substance be said to be "working for the city" in connection with the very market in which it was a market participant. For the two cases to be in any way analogous, Maine would

need to demonstrate that those affected by the Maine RX Program are in some "substantial if informal sense" a part of the Medicaid program. But, of course, those covered by the Maine Rx Program include all those who are *ineligible* to participate in Medicaid. Thus, *White* provides no support for Maine's position.

Indeed, the Court in *Wunnicke* explicitly rejected the broadened interpretation of *White* espoused by Maine. The Court explained that *White* turned on the fact that the hiring preference for city residents was limited to work that contractors were performing for Boston. *Wunnicke,* 467 U.S. at 97 n.10 (plurality). The market participant exception would have been inapplicable had Boston sought to extend its hiring preference "to the work force on all projects of any employer doing business with the city" (*id.*), even though Boston undoubtedly had just as much interest in encouraging employment of its residents on those other projects as it had in encouraging their employment in connection with projects being performed for the city. Similarly, that Maine has as great an interest in procuring low-cost prescription drugs for all its residents as it does in procuring such drugs for Medicaid recipients does not support Maine's efforts to invoke the market participant exception in this case.

Finally, *amici* note that a principal rationale for the market participant exception has been to permit States that act in a proprietary capacity to compete on an equal basis with private entities. As the Supreme Court explained in *Reeves*:

> [S]tate proprietary activities may be, and often are, burdened with the same restrictions imposed on private market participants. Evenhandedness suggests that, when acting as proprietors, States should similarly share existing freedoms from federal restraints, including the inherent limits of the Commerce Clause.

Reeves, 447 U.S. at 439. That rationale has no application to this case. Maine's operation of the Medicaid program does not even remotely resemble the types of "state proprietary activities" at issue in *Alexandria Scrap, Reeves,* or *White*, nor need Maine worry about its ability to compete on an equal footing with competing Medicaid providers. Accordingly, there can be no justification for immunizing Maine from the normal constraints imposed on State activity by the dormant Commerce Clause.

B. The Maine Rx Program Violates the Dormant Commerce Clause Because It Regulates Commerce Extraterritorially

The record is uncontested that virtually all prescription drugs sold in Maine were initially sold by drug companies to wholesalers in connection with transactions that took place wholly outside the State of Maine. Yet, the Maine Rx Program attempts to regulate such wholesale transactions by reducing the wholesale price by the amount of the rebate that manufacturers are required to pay to the State. Such State efforts to exert extraterritorial control over sales transactions lacking any significant nexus with the State constitute a *per se* violation of the Commerce Clause.

As the district court held, "bedrock principles concerning the territorial limits of a state's power" prohibit a State from attempting to "extend its authority to out-of-state manufacturers" in this manner. Pet. App. 64-65. This Court has repeatedly held that a State's efforts to control commerce occurring wholly outside the boundaries of the State are *per*

se invalid under the dormant Commerce Clause. The Court has explained:

> Taken together, our cases concerning the extraterritorial effects of state economic regulation stand at a minimum for the following propositions. First, the Commerce Clause precludes the application of a state statute to commerce that takes place outside of the State's borders, whether or not the commerce has effects within the State. [Citations omitted.] . . . Second, a statute that directly controls commerce wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature.

Healy v. Beer Institute, 491 U.S. 324, 336 (1989). In *Healy*, the Court struck down a Connecticut law that required liquor wholesalers to affirm that their prices were no higher than the prices at which their products were sold in neighboring states, because the law had the inevitable impact of controlling wholesale prices in those neighboring States. *Id.* at 338.

Similarly, the Court struck down as a *per se* Commerce Clause violation a New York law that prohibited the sale in New York of milk which had been sold by milk producers in other states for less than New York's minimum producer price. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935). Justice Brandeis wrote for the Court in that case:

> New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there. So much is not disputed. New

> York is equally without power to prohibit the introduction within her territory of milk of wholesome quality acquired in Vermont, whether at high prices or low ones.

Id. at 522.

Maine makes a half-hearted attempt to insist that it is not really regulating out-of-state drug sales at the wholesale level. Maine Opp. Br. 18 ("[T]he Maine Rx statute does not have th[e] effect [of regulating extraterritorial prices]. Simply put, it does not tie in-state prices to pricing elsewhere. It does not constrain manufacturers' pricing freedom."). That argument is without merit. It is uncontested that the amount of the rebate is tied directly to the volume of a manufacturer's drugs ultimately sold within Maine. Accordingly, each dollar of the rebate can be traced to a specific wholesale transaction that took place wholly outside Maine. Maine is correct, of course, that it does not dictate to manufacturers the precise wholesale price at which they must sell their drugs. But it cannot seriously be disputed that Maine is directly regulating those wholesale transaction: it is directing that the net wholesale price be reduced by the amount of the Maine Rx Program rebate.

The Commerce Clause does not, of course, constrain Maine's power to impose price controls on retail sales occurring within the State. But Maine has chosen not to pursue that path. Instead of imposing economic burdens on in-state pharmacists, it has attempted to impose those burdens on out-of-state drug manufacturers who, for the most part, have not engaged in any economic transactions within the State. Maine insists that the effect of its decision is not significantly different than if it had sought to regulate prices

at the retail level. We do not, of course, know the answer to that question. We do know, however, that the Supreme Court has stated in no uncertain terms that States' attempts to regulate extraterritorially in the manner adopted by Maine are *per se* invalid under the Commerce Clause.

Maine's effort to distinguish this case from *Healy* and other price control cases is unavailing. Both *Healy* and *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986), struck down as *per se* violations of the Commerce Clause state laws that required liquor wholesalers to affirm that their prices were no higher than the prices at which their products were sold in neighboring states. *Baldwin* struck down as a *per se* Commerce Clause violation a New York law that prohibited the sale in New York of milk which had been sold by milk producers in other states for less than New York's minimum producer price. Maine insists that *Baldwin, Healy*, and *Brown-Forman* are distinguishable because in each case, the challenged statute tied "the in-state price to those charged in another state." Maine Opp. Br. 18. Maine notes that the Maine Rx Program makes no effort to tie in-state and out-of-state prices. *Id.* That is no distinction at all, because (unlike the challenged statutes in *Baldwin, Healy,* and *Brown-Forman*) the Maine Rx Program operates directly on out-of-state prices. It was necessary for the plaintiffs in *Baldwin, Healy,* and *Brown-Forman* to demonstrate that in-state prices were tied to out-of-state prices because the challenged statutes did not on their faces purport to regulate out-of-state prices; it was only by demonstrating a tie-in that the plaintiffs could show that the States' regulation of in-state prices inevitably resulted in the regulation of out-of-state prices. Because the Maine Rx Program directly regulates out-of-state wholesale prices, there is no need for PhRMA to demonstrate a tie-in between

in-state and out-of-state prices,[3] and thus *Baldwin, Healy,* and *Brown-Forman* cannot be distinguished on that basis.

Maine also argued in the appeals court that, even if the extraterritoriality of State regulation can raise Commerce Clause concerns, such concerns can never amount to *per se* violations of the dormant Commerce Clause. Maine Court of Appeals Br. 42-50. That argument utterly fails to address the Court's language in *Healy* and similar cases that "the Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside the State's borders, whether or not the commerce has effects within the State." *Healy,* 491 U.S. at 336 (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion)).

The United States warns against the allegedly dire consequences of adpting PhRMA's view of the Commerce Clause:

> Indeed, petitioner's broad reasoning would condemn a wide variety of permissible state regulations that may affect the conduct of out-of-state manufacturers for the in-state sale of defective or unreasonably dangerous drugs or requiring that all automobiles sold in-state meet state emissions standards.

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[3] Because the Rx Program rebate is tied to the Medicaid rebate and the Medicaid rebate determines a nationwide price for prescription drugs sold under the Medicaid program, a strong case can be made nonetheless that the Rx Program rebate *is* directly tied to out-of-state prescription drug prices.

U.S. Br. 17. The United States's concerns are not well founded. A State is free to regulate sales of goods within its borders. Such regulation may encompass not only the sales price but also the quality of goods sold; if the goods are defective, the State may sanction all parties responsible for bringing about the sale of defective goods. But what it may not do is regulate sales transactions that take place outside its borders, regardless whether the goods sold eventually make their way into the State.

Maine also argued that *Healy* and similar cases are outdated and have been replaced by a more modern Commerce Clause jurisprudence that eschews a *per se* approach to dormant Commerce Clause issues. In support of that proposition, Maine cited several Supreme Court decisions that have focused on discrimination against interstate commerce as the principal concern of the dormant Commerce Clause. *See, e.g.*, Maine Appeals Court Br. at 43 (citing *CTS Corp. v. Dynamics Corp. of America,* 481 U.S. 69, 87 (1987), for the proposition that "[t]he principal objects of dormant Commerce Clause scrutiny are statutes that discriminate against interstate commerce"). Noting that the Maine Rx Program does not discriminate between in-state and out-of-state drug manufacturers (indeed, there are no in-state manufacturers), Maine argued that the Program should not be subjected to *per se* invalidation. *Id.* 42-50.

But none of the case law cited by Maine indicates that discrimination against interstate commerce should be the *sole* ground for finding State regulation *per se* invalid under the dormant Commerce Clause, or that *Healy* and *Brown-Forman* (which were decided in 1989 and 1986, respectively) are no longer good law. Indeed, in a more recent decision, the Supreme Court gave a ringing endorsement to *per se*

invalidity rules outside of the context of discrimination against interstate commerce. In *Quill Corp. v. North Dakota,* 504 U.S. 298 (1992), the State of North Dakota sought a declaratory judgment that out-of-state mail-order companies shipping goods into North Dakota were required to collect and remit use tax based on the value of the goods shipped. The Supreme Court held that any effort by a State to collect such use taxes from mail order companies would be a *per se* violation of the dormant Commerce Clause where the company had no connection with the taxing state other than that its goods eventually made their way into the State. *Quill Corp.*, 504 U.S. 309-318. While noting that such State tax collection efforts would in no way discriminate against interstate commerce, the Court held that the dormant Commerce Clause also "bars state regulations that unduly burden interstate commerce." *Id.* at 312. In establishing a *per se* rule that State tax collection efforts against out-of-state mail order companies would, in fact, "unduly burden interstate commerce," the Court recognized that such a rule "appears artificial at its edges" because, for example, "Whether or not a State may compel a vendor to collect a sales or use tax may turn on the presence in the taxing State of a small sales force, plant or office." *Id.* at 315. The Court nonetheless chose to adopt a *per se* rule because any "artificiality . . . is more than offset by the benefits of a clear rule." *Id.* The Court added:

> A bright-line rule in the area of sales and use taxes also encourages settled expectations and, in doing so, fosters investment by businesses and individuals.

Id. at 316.

Quill Corp.'s rationale is equally applicable here. The Court has long maintained a clear distinction between State efforts to control interstate commerce that occurs within the State's boundaries and efforts to control interstate commerce outside those boundaries. The latter have repeatedly been held *per se* invalid under the dormant Commerce Clause. It may be true that there will be cases in which this distinction appears somewhat artificial. It may be that Maine could accomplish a major portion of what the Rx Program seeks to accomplish without resorting to regulation of wholesale drug sales occurring wholly outside the State. Nonetheless, the clear prohibition against extraterritorial application of State regulations has stood the test of time; it provides a bright-line rule that "encourages settled expectations" and "fosters investment." That rule should not be lightly cast aside.

Amici note, moreover, that if Maine is free to regulate wholesale drug prices extraterritorially, then other States would be free to attempt to regulate retail prices in Maine. A State in which drug manufacturers maintain their principal place of business might, for example, seek to maintain minimum retail drug prices in Maine, assuming that they possessed market leverage that they could use for that purpose. By prohibiting States from regulating extraterritorially, the dormant Commerce Clause guards against that possibility.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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IN THE

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PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA,
Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE
DEPARTMENT OF HUMAN SERVICES, *et al.*,
Respondents.

**On Writ of Certiorari to the
United States Court of Appeals
for the First Circuit**

BRIEF FOR THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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BRIEF FOR THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF PETITIONER

STATEMENT OF INTEREST

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation.[1]

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[1] No counsel for any party authored this brief in whole or in part, and no person or entity, other than the amicus curiae and its members, made a monetary contribution to the preparation or submission of this brief. S. Ct. Rule 37.6. The brief is filed with the

It represents an underlying membership of more than three million businesses and organizations in every industrial sector and geographic region of the country. The Chamber has participated as amicus curiae in several hundred cases before this Court, including numerous cases addressing the Supremacy Clause, *see, e.g.*, *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363 (2000); *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000); *United States* v. *Locke*, 529 U.S. 89 (2000), and the Commerce Clause, *see, e.g.*, *Crosby*, 530 U.S. 363; *General Motors Corp.* v. *Tracy*, 519 U.S. 278 (1997). The Chamber filed a brief supporting the petition for certiorari in this case.

SUMMARY OF ARGUMENT

The Maine Rx Act's prior-authorization regime is preempted by the federal Medicaid Act. The Medicaid Act directs States administering Medicaid programs—including Maine—to administer the Medicaid program in keeping with the best interests of Medicaid recipients. Maine's Rx Act, however, directs that manufacturers who do not agree to pay "rebates" to Maine to fund a prescription drug plan that benefits all state residents *except* Medicaid recipients will have their drugs placed on Medicaid prior-authorization status—meaning that Medicaid recipients and their physicians must seek approval before those drugs may be prescribed. There is no Medicaid-related reason for such drugs to be placed on prior-authorization status; a manufacturer's refusal to enter into the *non*-Medicaid "rebate" arrangement is the only predicate to the prior-authorization determination.

The burden of prior authorization, however, is borne by Medicaid recipients. For drugs designated by the State as requiring prior authorization, Medicaid recipients must seek prior approval from the State before they may be prescribed

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consent of the parties, and copies of the consent letters have been filed with the Clerk.

drugs they once received as a matter of course. Indeed, the State conceded below that some Medicaid recipients will not receive their first-choice drugs at all as a result of the prior authorization requirement. Maine's use of Medicaid prior authorization as a coercive tool to fund its non-Medicaid Rx Program is squarely at odds with the Medicaid Act's directive that the Act and its terms be administered in the best interests of *Medicaid* recipients.

The Rx Act also conflicts with the Commerce Clause. This Court has repeatedly held that a State may not enact legislation regulating transactions taking place wholly outside its borders. Yet that is exactly what the Rx Act does, by imposing "rebate" obligations on out-of-state manufacturers who contract out-of-state with predominantly out-of-state wholesalers. The Act not only improperly changes the terms of a transaction occurring outside Maine; its prior-authorization regime, coupled with its draconian "no-exit" anti-retaliation provisions, forces manufacturers to recoup their lost revenues by charging consumers in *other* States more for their prescription drugs. And if other States, spurred by increasing prescription drug costs in their own jurisdictions, follow Maine's lead, the impact on interstate commerce and the drug industry will be substantial and grave. The First Circuit's decision should be reversed.

ARGUMENT

I. THE RX ACT IS PREEMPTED BY THE FEDERAL MEDICAID ACT.

1. The Medicaid Act, 42 U.S.C. § 1396 *et seq.*, is a cooperative venture between the federal government and the States, "designed to provide medical assistance to persons whose income and resources are insufficient to meet the costs of necessary care and services." *Atkins* v. *Rivera*, 477 U.S. 154, 157 (1986); 42 U.S.C. § 1396. The Act requires States, in exchange for federal funding, to provide Medicaid benefits

to the "categorically needy"—those eligible for financial assistance under either the Supplemental Security Income for the Aged, Blind, and Disabled (SSI) program or the Aid to Families with Dependent Children (AFDC) program. *Atkins*, 477 U.S. at 156; *see* 42 U.S.C. § 1396a(a)(10)(A)(i)(IV), (VI), (VII). "[O]ne is eligible for AFDC or SSI only if, in a given month, he or she earns less than what has been determined to be required for the basic necessities of life." *Atkins*, 477 U.S. at 156. The Medicaid program also permits States to extend benefits to the "medically needy"—"persons lacking the ability to pay for medical expenses, but with incomes too large to qualify for categorical assistance." *Schweiker* v. *Gray Panthers*, 453 U.S. 34, 37 (1981); *see* 42 U.S.C. § 1396a(a)(10)(C).

Every State operates its own Medicaid program, jointly funded by state and federal contributions. *See* 42 U.S.C. § 1396a; *see also* 22 Me. Rev. Stat. Ann. § 3174 (describing eligibility requirements for Maine Medicaid program, which provides assistance to state residents lacking "sufficient income or other resources to provide a reasonable subsistence compatible with decency and health"). States must submit their Medicaid program plans to the federal government for approval, and the plan must "provide such safeguards as may be necessary to assure that * * * care and services will be provided, in a manner consistent with simplicity of administration and the best interests of [Medicaid] recipients." 42 U.S.C. § 1396a(a)(19). *See Harris* v. *McRae*, 448 U.S. 297, 309 (1980).

2. Concluding that state residents were paying too much for prescription drugs, Maine's legislature passed a law titled "An Act to Establish Fairer Pricing for Prescription Drugs," 2000 Me. Legis. Ch. 786—the "Rx Act" for short. The Rx Act was enacted "to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities

and protecting the public health and welfare." 22 Me. Rev. Stat. Ann. § 2681(1).

The Rx Act requires every drug manufacturer whose products ultimately are sold in the State to "enter into a rebate agreement" with Maine's Department of Human Services, and to make rebate payments to the State each calendar quarter—an arrangement similar to the federal prescription drug rebate program set forth in the Medicaid statute. *Id.* § 2681(3).[2] The Commissioner of the Department of Human Services must "negotiate the amount of the rebate required" under the Rx Act and must use his "best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program." *Id.* § 2681(4)(B). The rebates obtained under the Rx Act are used to compensate participating retail pharmacies for providing discounted drug prices to Maine residents. *Id.* § 2681(9). The Rx Act is not limited to those eligible for Medicaid but is instead "open to all State residents." Pet. App. 3.

Drug manufacturers who do not enter into rebate agreements under the Rx Act face severe penalties. The Act directs the State Department of Human Services to impose Medicaid prior-authorization requirements "for the dispensing of prescription drugs provided by those manufacturers" who do not meet the State's terms. 22 Me. Rev. Stat. Ann. § 2681(7). Subjecting a drug to prior authorization under the Medicaid statute means that prescribing physicians must seek approval from state Medicaid officials before the drug may be dispensed. *See* 42 U.S.C. § 1396r-8(d)(1)(A).

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[2] The Medicaid statute contains a mechanism for collecting "rebates" from manufacturers supplying drugs to Medicaid recipients. 42 U.S.C. § 1396r-8. Put simply, manufacturers pay rebates to each State based on the number of units of their drugs dispensed to Medicaid beneficiaries and paid for by the State under its Medicaid plan, pursuant to a formula set forth in the statute. *See id.*

The Rx Act further provides that *any* manufacturer—whether it pays the required rebates or not—who "[i]ntentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in [Maine] in retaliation for the provisions of" the Rx Act is deemed to have "engage[d] in illegal profiteering." 22 Me. Rev. Stat. Ann. § 2697(2)(D). Manufacturers who violate this "profiteering" prohibition are subject to injunctive relief and civil penalties of $100,000 for each violation, an action by the State for treble damages, and additional claims for punitive damages for "willful or repeated violation[s]" of the law. *Id.* § 2697(3)-(4).

3. The Supremacy Clause "requires the invalidation of any state legislation that burdens or conflicts in any manner with any federal laws." *De Canas* v. *Bica*, 424 U.S. 351, 357 n.5 (1976); U.S. Const. art. VI, cl.2. A state law conflicts with federal law if it " 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'—whether that 'obstacle' goes by the name of 'conflicting; contrary to; * * * repugnance; difference; irreconcilability; inconsistency; violation; curtailment; * * * interference,' or the like." *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 873 (2000) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)); *see also Savage* v. *Jones*, 225 U.S. 501, 533 (1912).

The Maine Rx Act's prior authorization regime conflicts with the Medicaid Act and is therefore preempted. The state law directs the Commissioner of Maine's Department of Human Services to subject to Medicaid prior-authorization requirements the drugs of any manufacturer who refuses to enter into Rx Act "rebate" agreements. The necessary result of that directive is that drugs will be placed on prior authorization status not for any *Medicaid*-related reason, but solely because manufacturers decline to participate in *another* state-run program.

The burden of prior authorization, however, falls squarely on Medicaid beneficiaries. If Medicaid recipients' first-choice prescription drugs are subject to prior authorization, recipients and their doctors will be forced to seek affirmative permission from the State before those drugs may be dispensed—where before the Rx Act, those drugs were regularly dispensed without prior authorization. And Medicaid recipients forced to seek prior authorization may not get their first-choice drugs at all: Maine conceded in the Court of Appeals that it "will not authorize payment for the first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant." Pet. App. 15.

The Rx Act's use of the prior-authorization requirement in a manner that impedes or frustrates Medicaid recipients' access to their first-choice prescription drugs conflicts with the Medicaid Act's express directive to administer the state Medicaid program in keeping with "the best interests of [Medicaid] recipients." 42 U.S.C. § 1396a(a)(19); *Davis* v. *Elmira Savings Bank*, 161 U.S. 275, 283 (1896) (state law is preempted if it "either frustrates the purpose of the national legislation or impairs the efficiency of those agencies of the Federal government to discharge the duties, for the performance of which they were created"). It is plainly not in the best interests of Medicaid recipients to force their physicians to seek administrative permission from the State before recipients may be prescribed the drug of their choice—for wholly collateral reasons having nothing to do with the Medicaid program. Nor is it in the best interests of Medicaid recipients to force them to accept a second- or third-choice drug in place of their first choice, for no reason other than that the first-choice manufacturer will not participate in a separate state program. *See* U.S. Br. (petition stage) 11 (noting that "the State program on its face is designed to serve the State's *non-Medicaid* population by imposing a burden on the ability of *Medicaid* recipients to receive an otherwise covered outpatient drug") (emphases in original).

The First Circuit concluded otherwise, opining that so long as Maine administered the prior authorization requirements " '[a]s permitted by law' "—that is, provided for 24-hour notice of approval or declination, and allowed for dispensation of a 72-hour supply of a drug—the State would not run afoul of the Medicaid Act. Pet. App. 11 (quoting 22 Me. Rev. Stat. Ann. § 2681(7) and citing 42 U.S.C. § 1396r-8(d)(5)(A) and (B)); Pet. App. 11 n.7 (referencing affidavit from respondent Concannon purporting to affirm that prior authorization "would not conflict with the Medicaid requirements"). But that is not the proper question in this preemption inquiry. Whether the state law employs prior authorization in accordance with the Medicaid Act's *procedural* requirements is irrelevant. It is the Commissioner's use of prior authorization in the first place for a non-Medicaid purpose that burdens Medicaid recipients' access to their first-choice prescription drugs. The Act's procedural protections are cold comfort to a Medicaid recipient who is told (within 24 hours) that he must accept a different drug treatment than the one his doctor recommended and that he prefers, solely because the manufacturer of his first-choice drug will not contribute money to a wholly separate state program.

The First Circuit also concluded that the "purposes of the Medicaid statute, read broadly, are consonant with the purposes of the Rx Act." Pet. App. 13. According to the Court of Appeals, the state program "furthers Medicaid's aim of providing medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical services,' * * * even if the individuals covered by the Maine Rx Act are not poor enough to qualify for Medicaid." *Id.* (citing 42 U.S.C. § 1396a). That does not add up. The Medicaid Act provides for medical and drug coverage for a specified population of eligible people; it is that population to which the Act refers when it identifies those whose "income and resources are insufficient to meet the costs of necessary medical services," and it is on behalf of that population that States administer their Medicaid programs. The

Rx Act, on the other hand, affords drug discounts for *every* citizen in Maine not already receiving them under Medicaid—from the borderline Medicaid-ineligible to the well-off. Pet. App. 3. To say that a state law furthers the Medicaid Act's aims when it applies to—indeed, is specifically directed at—everyone in Maine *but* Medicaid recipients stretches the Medicaid Act's purpose beyond all credence.

The First Circuit also surmised that the Maine Rx Act could actually "reduce Medicaid expenditures" by making prescription drugs less expensive for Maine residents not on federal assistance. Pet. App. 13. The court suggested that if people not eligible for Medicaid nonetheless were "unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program." *Id.* But Medicaid's express charge to the States is to make coverage decisions under the Act that further the best interests of those *currently* receiving Medicaid assistance, *see* 42 U.S.C. § 1396a(a)(19)—not the interests of potential Maine Medicaid recipients, and certainly not the interests of those in Maine's middle and upper classes, who are equally eligible to participate in the Maine Rx Act.

Finally, the First Circuit concluded that petitioner PhRMA had not shown that the Maine Rx Act "on its face, controverts the Medicaid goal of 'best interests.' " Pet. App. 15. The court was wrong; PhRMA made out a compelling facial challenge to the state law. *See* U.S. Br. (petition stage) 11 (observing that the Rx Act "on its face is designed to serve the State's *non-Medicaid* population by imposing a burden on the ability of *Medicaid* recipients to receive an otherwise covered outpatient drug") (emphases in original). The proof is, among other places, in the Rx Act itself. The reason the prior authorization provision was considered by the Maine legislature to be an effective coercive tool was that prior authorization decreases a drug manufacturer's market share. The State did not contest PhRMA's affidavits to that effect in the District Court. *See* Pet. App. 71 (noting uncontested

"affidavits that a prior authorization listing often results in substantially reduced market share for a manufacturer"). Reduced market share means fewer drugs are being sold, because Medicaid recipients are not getting the first-choice drugs they previously were prescribed and received without encumbrance or delay.

This Court in similar circumstances has not hesitated to find a state law preempted, even without concrete evidence that the conflict apparent on the face of the statute would actually come to pass. The Illinois licensing law at issue in *Gade* v. *National Solid Wastes Management Ass'n*, 505 U.S. 88, 94 (1992), for example, was challenged before it went into effect. No one required the respondent there to gather concrete evidence that the onerous state requirement in fact precluded some of its members from being state-licensed; that was plain from the state law's terms. So too here. The Rx Act on its face hampers—and as the State concedes, in some cases forecloses—Medicaid recipients' access to the drugs of their choice. If the law did not have that effect—if it did not result in a direct impact on a manufacturer's sales—it would wholly fail to achieve the purposes of its sponsors.

The First Circuit panel stressed that it was particularly reluctant to find preemption where a state statute implicated a coordinated federal-state aid program: " '[w]here coordinate[d] state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal pre-emption becomes a less persuasive one.' " Pet. App. 10 (quoting *New York State Dep't of Social Servs.* v. *Dublino*, 413 U.S. 405, 421 (1973)). But that formulation assumes what the Rx Act lacks: that the state law is "in pursuit of common purposes" with the federal statute. The Rx Act's prior authorization provision does not even purport to pursue a purpose in common with the Medicaid program. *See* Pet. App. 71 ("The State makes no argument that the * * * condition of prior approval serves any

purpose of the Medicaid program.").[3] The prior-authorization provision was put in place to force manufacturers to contribute to the Rx fund, at the expense of Medicaid recipients' unencumbered access to the prescription drugs of their choice.

To be sure, a State may impose a prior authorization requirement on certain drugs before the drugs may be prescribed for Medicaid patients, *see* 42 U.S.C. § 1396r-8(d)(1)(A), but any prior authorization requirement must further the best interests of Medicaid recipients. For example, drugs with serious cumulative side effects over time, those that are overprescribed, or those with serious addictive potential might legitimately be subject to prior authorization, if Medicaid administrators concluded that doing so was in the best interests of Medicaid patients. *See* Pet. App. 71 n.14 (noting affidavit from the Medical Director for the Maine Bureau of Medicaid Services stating that "the primary purpose of a prior authorization requirement is to ensure that a drug is not being used inappropriately"). What the State may *not* do is impose Medicaid prior authorization requirements that lack any pretense of a legitimate Medicaid rationale, and then employ those requirements in a manner that impairs the interests of Medicaid recipients in order to benefit an entirely separate, non-Medicaid-eligible, population. The Rx Act's prior authorization provision is preempted.

II. THE RX ACT VIOLATES THE COMMERCE CLAUSE.

The Commerce Clause grants Congress the power to "regulate Commerce * * * among the several States." U.S. Const. art. I, § 8, cl. 3. The Clause has long been held to carry an "implied limitation" on States' power to interfere with inter-

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[3] In *Dublino*, moreover, this Court remanded to the court of appeals to consider "the issue of specific conflict between the state and federal programs" at issue there, after holding that federal law did not *entirely* preempt the State's program. 413 U.S. at 422.

state commerce. *Western & Southern Life Ins. Co.* v. *State Bd. of Equalization of Cal.*, 451 U.S. 648, 652 (1981). This implicit prohibition is directed at state regulation "that discriminates against or unduly burdens interstate commerce and thereby 'imped[es] free private trade in the national marketplace.' " *General Motors Corp.* v. *Tracy*, 519 U.S. at 287 (quoting *Reeves, Inc.* v. *Stake*, 447 U.S. 429, 437 (1980)); *see also H.P. Hood & Sons* v. *Du Mond*, 336 U.S. 525, 534-535 (1949); *Welton* v. *Missouri*, 91 U.S. 275 (1876).

The "Commerce Clause * * * precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Edgar* v. *MITE Corp.*, 457 U.S. 624, 642-643 (1982) (plurality opinion); *see Dean Foods Co.* v. *Brancel*, 187 F.3d 609, 615 (7th Cir. 1999) ("There is a long line of cases holding that states violate the Commerce Clause by regulating or controlling commerce occurring wholly outside their borders."). If the "practical effect" of a state statute is to control commerce occurring outside the State, the statute "exceeds the inherent limits of the enacting State's authority and is invalid." *Healy* v. *Beer Inst.*, 491 U.S. 324, 336 (1989); *see also Maine* v. *Taylor*, 477 U.S. 131, 138 (1986).

The Rx Act fails that test. The law imposes conditions on transactions occurring wholly outside Maine, and it forces consumers in other States to subsidize the Maine legislature's policy choice. And if more States follow Maine's lead—an issue this Court traditionally examines in Commerce Clause challenges—the impact on interstate commerce, and on the drug manufacturing industry generally, will be severe.

1. Every drug manufacturer PhRMA represents is located outside Maine. Pet. App. 60. "[B]y far the greater bulk of their customers—wholesalers and distributors—are likewise

outside Maine." *Id.*[4] Manufacturers sell to wholesalers or distributors "at [a] place of business outside Maine" (with one exception, *see* n.4), and those wholesalers or distributors in turn contract with retailers in the State to sell the drugs. *Id.* Maine's Rx Act requires those out-of-state manufacturers—who contract out-of-state with predominantly out-of-state entities—to pay "rebates" to the State for the benefit of state residents participating in the Rx Program, based on the number of units of their drugs ultimately sold by others in the State. The Act thus is directed at entities that do not themselves transact business in Maine, and it effectively changes the terms of transactions between manufacturers and wholesalers that do not occur in Maine. The Rx Act's regime bears the same stamp as the state laws this Court struck down in *Baldwin* v. *G.A.F. Seelig, Inc.*, 294 U.S. 511, 519 (1935), *Brown-Forman Distillers Corp.* v. *New York State Liquor Auth.*, 476 U.S. 573, 575 (1986), and *Healy* v. *Beer Institute*, 491 U.S. at 327, and it, too, should fall.

In *Baldwin*, 294 U.S. at 519, this Court examined a New York law prohibiting the sale in the State of milk bought outside the State unless the price paid to out-of-state milk producers "was one that would be lawful upon a like transaction within the state." Finding that New York had improperly "project[ed] its legislation" beyond its boundaries, the Court struck down the law. *Id.* at 521. As the Court explained, a State may not bolster its citizens' economic interests at another State's expense; "commerce between the states is burdened unduly when one state regulates by indirection the prices to be paid to producers in another." *Id.* at 524.

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[4] The District Court noted three "limited exceptions" where distributors or wholesalers operated facilities in Maine, but observed that two of those three entities contracted outside the State to import drugs to Maine. Just one distributor operates facilities in Maine and contracts with a drug manufacturer in the State. Pet. App. 60.

Similarly, in *Brown-Forman*, 476 U.S. at 575, the Court examined a New York statute requiring every liquor distiller or producer that sold liquor to wholesalers in the State to sell at a price that was "no higher than the lowest price the distiller charges wholesalers anywhere else in the United States." The state law violated the dormant Commerce Clause, the Court concluded, because it effectively "regulat[ed] out-of-state transactions" by prohibiting producers from changing their prices in other States. *Id.* at 582. The fact that the law applied evenhandedly to all producers and distillers was irrelevant: "Economic protectionism is not limited to attempts to convey advantages on local merchants; it may include attempts to give local consumers an advantage over consumers in other States." *Id.* at 580 (citing *New England Power Co.* v. *New Hampshire*, 455 U.S. 331, 338 (1982)).

Finally, in *Healy*, 491 U.S. at 327, the Connecticut legislature, seeking to reduce prices of beer sold in the State, enacted a statute requiring out-of-state brewers and shippers to affirm that their prices in Connecticut "were and would remain no higher than the lowest prices they would charge for each beer product in the border States." The Court struck the statute down, finding that it "has the undeniable effect of controlling commercial activity occurring wholly outside the boundary of the State." *Id.* at 337. By linking in-state beer prices to the price of transactions in neighboring States, the state law had the "extraterritorial effect, condemned in *Brown-Forman*," of preventing brewers from altering their pricing in other States to accommodate changing market conditions. *Id.* at 338. Because the law improperly benefited Connecticut consumers at the expense of those in other States, it could not stand. *Id.* at 339.

The Court should reach the same result here as it did in *Healy*, *Brown-Forman*, and *Baldwin*. As the Court explained in *Healy*, "[t]he critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries

of the State." 491 U.S. at 336. And as the District Court correctly recognized, "the practical effect of what Maine has done here is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine." Pet. App. 66. That arrangement is exactly the sort of regime condemned in *Healy* and its predecessor cases.

The First Circuit glibly distinguished those cases by concluding that they "involve[d] price control, price affirmation or price tying," while the Rx Act implicated manufacturers' revenues. Pet. App. 21; *see id.* at 23. But the Commerce Clause prohibits States from creating impediments to interstate commerce, not just from fixing interstate prices.[5] *See, e.g.*, *New England Power Co.* v. *New Hampshire*, 455 U.S. at 335; *Hunt* v. *Washington State Apple Adver. Comm'n*, 432 U.S. 333, 351 (1977); *Pike* v. *Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); *see also Louisiana Dairy Stabilization Bd.* v. *Dairy Fresh Corp.*, 631 F.2d 67, 69 (5th Cir. Unit A 1980) (finding "ineffectual" respondents' proposed distinction between "attempts at fixing the price of out-of-state products" and other extraterritorial regulation), *aff'd*, 454 U.S. 884 (1981).

This Court has also rejected the notion that a state law with an improper extraterritorial effect is legitimate if it only impacts manufacturers' revenues. In *West Lynn Creamery, Inc.*, v. *Healy*, 512 U.S. 186, 195 & n.11 (1994), petitioner challenged a state pricing order requiring every milk dealer operating in Massachusetts to make "premium payments" into a state fund based on their sales to state retailers, to be

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[5] As PhRMA explained below, moreover, the Rx Act *does* impermissibly tie prices. The rebates manufacturers pay to the State are linked to Medicaid rebates set at the national level, and thus are affected by price changes in other States; if a manufacturer lowers its price in Virginia and that price becomes the new "best price" for Medicaid rebates, the manufacturer will pay a higher Rx Act rebate in Maine.

distributed to Massachusetts dairy farmers. *Id.* at 190. This Court found the order to violate the Commerce Clause, because it effectively imposed a tax on out-of-state milk. *Id.* at 194.[6] The Court observed that in certain circumstances, out-of-state milk producers might still remain competitive in the Massachusetts market by cutting their prices—and thus sacrificing their profits—but the Court recognized that that possibility "would not immunize a discriminatory measure." *Id.* at 195.

The Court reached a similar conclusion in *New Energy Co. of Indiana* v. *Limbach*, 486 U.S. 269, 275 (1988), rejecting the contention that a state law that "only" placed out-of-state products at a "commercial disadvantage" comported with the Commerce Clause. The *New Energy* Court observed that the appellant in *Baldwin* v. *G.A.F. Seelig, Inc.*, "in order to sell [milk] in New York, only had to cut its profits by increasing its purchase price above the market price sufficiently to meet the New York-prescribed premium." 486 U.S. at 269. Similarly, the petitioner in *New Energy*, "in order to sell its product in Ohio, only ha[d] to cut its profits by reducing its sales price below the market price sufficiently to compensate the Ohio purchaser-retailer for the forgone tax credit." *Id.* But the state regime in *Baldwin* was held to be " 'an economic barrier against competition' that was 'equivalent to a rampart of customs duties,' " *id.* (quoting *Baldwin*, 294 U.S. at 527), and the law at issue in *New Energy* met a similar fate. 486 U.S. at 279. So too here. The fact that Maine's extraterritorial forced rebate arrangement "only" operates to reduce manufacturers' revenues does not insulate it from a Commerce Clause challenge.

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[6] The pricing order applied to all milk sales in the State, but its "effect on Massachusetts producers [wa]s entirely (indeed more than) offset by the subsidy provided exclusively to Massachusetts dairy farmers." *Id.* at 194.

The First Circuit more fundamentally disagreed that the Rx Act was directed at out-of-state transactions, opining that the Act "[u]ltimately * * * simply regulates activity that occurs in state: (1) the purchase of the prescription drugs that triggers the rebate; (2) the negotiation of a rebate amount; and (3) the State's action subjecting a manufacturers' drug to prior authorization and releasing the manufacturer's name to health care providers and the public [all] occur[] in state." Pet. App. 24. This Court confronted a similar line of argument in *Brown-Forman* and rejected it: "The mere fact that the effects of New York's ABC Law are triggered only by sales of liquor within the State of New York * * * does not validate the law if it regulates the out-of-state transactions of distillers who sell in-state." 476 U.S. at 580. Exactly so here. The transaction that the Rx Act purports to regulate is that between out-of-state drug manufacturers—the only entities responsible for Rx Act "rebates"—and the predominantly out-of-state distributors with whom those manufacturers contract. The Act is invalid under *Healy*, *Brown-Forman*, and *Baldwin*. *See also Dean Foods*, 187 F.3d at 617 ("extraterritoriality principles ban a state from regulating 'sales that take place wholly outside it' ") (quoting *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 613 (7th Cir. 1997), *cert. denied*, 522 U.S. 1153 (1998)).

The First Circuit also suggested that because the Rx Program is "voluntary," the provisions of the Rx Act did not violate the Commerce Clause. Pet. App. 23. But a Hobson's choice is no choice at all. The Act directs that manufacturers "*shall* enter into a rebate agreement" with the State, and that they are "*require[d]*" to pay the rebate to the State each calendar quarter. 22 Me. Rev. Stat. Ann. § 2681(3) (emphasis added). The Commissioner is similarly directed to use his "best efforts" during one-sided "negotiat[ions]" with the manufacturers over the amount of the "rebate *required*," to obtain a rebate amount at least equal to the Medicaid rebate. *Id.* § 2681(4)(A)-(B) (emphasis added). Manufacturers have absolutely no leverage in their "negotiations" with the Com-

missioner: if they decline to pay the "required" rebates, or offer anything less than an amount equal to or greater than the Medicaid rebate, the State may terminate negotiations and direct that the manufacturer's drugs be placed on the Medicaid prior-authorization list, whereupon the manufacturer's market share plummets. *See* Pet. App. 71. If a manufacturer attempts to avoid or minimize the effect of the prior authorization regime by directing less of its product to the State, it will be sued for treble damages. And even if a manufacturer bends to the State's coercive terms and agrees to pay rebates, the manufacturer may not adjust its transactions in the State to minimize the impact of those rebates on its revenues; that, too, would trigger an action for treble damages. The Rx Act, in other words, is a coercive statute from all angles; there is nothing remotely "voluntary" about its operation.

2. The Maine Rx Act also has a discriminatory effect on out-of-state commerce—and on out-of-state consumers in particular—because of two especially pernicious aspects of its construction. In a freely operating interstate market, a manufacturer confronted with an onerous state tax or regulatory regime can do one of two things: it can increase prices to consumers within the State, or it can take steps to limit the flow of its products into the State. *See, e.g.*, *National Elec. Mfrs. Ass'n* v. *Sorrell*, 272 F.3d 104, 110-111 (2d Cir. 2001), *cert. denied*, 122 S. Ct. 2358 (2002).[7]

The Rx Act takes those options off the table. Drug manufacturers who have agreed to pay rebates cannot increase drug prices in Maine to recoup lost revenues; their rebate obligations will simply increase accordingly. Nor, as we

[7] It of course would not be a defense to a Commerce Clause challenge to extraterritorial or unconstitutionally protectionist state legislation that a manufacturer is free to stop selling its product in the State. The Clause guarantees a national market—not a choice between participating or not in a Balkanized one.

have just explained, can any manufacturer—whether an Rx Act participant or an Rx Act dissenter who has lost substantial market share because of prior authorization—restructure its transactions with wholesalers to avoid any ultimate sale of its drugs in Maine. Manufacturers face severe civil penalties and punitive damages if they seek to avoid sales in the State because of the operation of the Rx Act. *See* 22 Me. Rev. Stat. Ann. §§ 2697(2)(D), (3)-(4). Because Maine has foreclosed the two options normally available to manufacturers confronted with an increased cost of doing business in a particular State, manufacturers can recoup their lost revenues only *outside* Maine—by charging consumers in other States more for their prescription drugs. The dormant Commerce Clause forbids that result. *See Brown-Forman*, 476 U.S. at 580 ("While a State may seek lower prices for its consumers, it may not insist that producers or consumers in other States surrender whatever competitive advantages they may possess"); *South Carolina State Highway Dep't* v. *Barnwell Bros.*, 303 U.S. 177, 184 n.2 (1938) ("State regulations affecting interstate commerce, whose purpose or effect is to gain for those within the state an advantage at the expense of those without" violate Commerce Clause); *National Elec. Mfrs. Ass'n*, 272 F.3d at 110 (regulatory regime in *Healy* and similar cases unconstitutional because "the state necessarily prevented firms from recouping any of the costs imposed by state statute from the residents of the state itself"); *cf. New Hampshire Auto Dealers Ass'n* v. *General Motors Corp.*, 801 F.2d 528, 531 (1st Cir. 1986) (Breyer, J.) (recognizing dormant Commerce Clause implications if state consumer-protection law forced manufacturers to increase prices in other States, "thereby hurting the consumers who live there").

3. This Court in *Healy* directed that the "practical effect" of a state statute challenged under the Commerce Clause "must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory

regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." 491 U.S. at 336-337. The First Circuit concluded that the "most apparent effect of similar statutes being passed in other states would be a loss in profits for manufacturers," but concluded that on PhRMA's "facial challenge" to the Rx Act, the petitioner had shown "no evidence that adverse effects on interstate commerce will occur if such legislation were passed in other states." Pet. App. 24. That was wrong. If more States follow Maine's lead—strong-arming manufacturers into "rebate" schemes and imposing harsh "no-exit" penalties if manufacturers leave state markets to avoid the effect of those coercive schemes—interstate commerce, and drug manufacturing and innovation, will suffer gravely.

From the Constitution's creation through the present day, federal laws have protected manufacturers' revenue streams to encourage them to further innovate and refine their inventions. *See* U.S. Const. art. I, § 8; 35 U.S.C. § 154(a)(2). And in the drug industry in particular, Congress has repeatedly ensured that manufacturers who spend large sums of money to develop, test, gain federal approval of, and market a drug have a protected revenue stream for a period after the drug is approved for sale.[8] *See, e.g.*, 21 U.S.C. § 355(j)(C)(3)(D) (granting to "pioneer" drug manufacturers periods of market exclusivity ranging from two to ten years, depending on the drug's active ingredients); *id.* § 355a(a), (c) (granting terms of market exclusivity to drug manufacturers who perform pediatric studies); *id.* § 360cc (granting seven years market

[8] Manufacturers fund their research and development efforts with their revenues. *See* Jerry Stanton, Comment, *Lesson For The United States From Foreign Price Controls On Pharmaceuticals*, 16 Conn. J. Int'l L. 149, 153 (2000) ("The costs for traditional R&D efforts come from profits derived from the sale of products already in the marketplace, so current drug sales fund future research.") (citing Henry Grabowski, *Health Reform & Pharmaceutical Innovation* 19 (1994)).

exclusivity to manufacturers of "orphan drugs"—those aimed at treating a population of fewer than 200,000 people in the United States).

Congress has done so because developing new drugs is a long, risky, and astronomically expensive business. It takes ten to fifteen years to develop a new drug; the cost of developing a drug currently tops $800 million; and just three drug products out of every ten produce returns higher than their research and development costs. *See* PhRMA Industry Profile 2002, Ch. 2, "Research and Development: The Key To Innovation," at 12, 18-20, *available at* http://www.phrma.org/publications/publications/profile02/chapter2.pdf (last visited Sept. 19, 2002).[9]

If more States follow Maine's lead, two negative results will occur, one after the other. First, residents of States slow or reluctant to enact Maine's brand of policy fix would increasingly bear the brunt of the policy choice of the States following the Maine regime. And as more and more States protect their interests and enact Maine-style statutes, drug manufacturers' revenues will be siphoned off at an exponential rate. That in turn will have a direct effect on the resources manufacturers have at hand to devote to research and development efforts.

To be sure, States' nondiscriminatory regulatory efforts may impact manufacturers' revenues without running afoul of the Commerce Clause. Some such regulations further state residents' interests while impacting interstate commerce only glancingly. Others legitimately tax goods and services sold in the State. Maine's law has neither of those redeeming qualities. It extracts money from out-of-state manufacturers to benefit state residents, changing the terms of out-of-state

[9] *See also* S. Rep. No. 105-43, at 6-7 (1997) (study "suggested an average development time of fifteen years and average costs in the range of 500 million dollars per new drug").

transactions and forcing out-of-state consumers to pick up the tab for Maine's policy choice. The law should be struck down.

CONCLUSION

For the foregoing reasons, the judgment below should be reversed.

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IN THE

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PHARMACEUTICAL RESEARCH AND MANUFACTURES OF AMERICA,
Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF THE STATE OF MAINE,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF *AMICUS CURIAE* OF THE LONG TERM CARE PHARMACY ALLIANCE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. § 1396 *et seq.*, allows a state to use authority under that statute to compel drug manufacturers to subsidize price discounts for non-Medicaid populations?

CORPORATE DISCLOSURE STATEMENT

The Long Term Care Pharmacy Alliance (LTCPA) is a limited liability corporation representing five national long-term care pharmacy companies—Omnicare, Inc., PharMerica, Inc., NeighborCare, Inc., Kindred Pharmacy Services, Inc. and NCS Healthcare, Inc. LTCPA has neither a parent nor stockholders.

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On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF *AMICUS CURIAE* OF THE LONG TERM CARE PHARMACY ALLIANCE IN SUPPORT OF PETITIONER

INTEREST OF *AMICUS CURIAE*[1]

The Long Term Care Pharmacy Alliance (LTCPA) consists of five long-term care pharmacy companies that collectively dispense prescription drugs and provide consultant pharmacist services to more than 1.5 million patients. The patients served by LTCPA members include approximately two-thirds

[1] Pursuant to Sup. Ct. R. 37(3)(a), the Parties have consented to the submission of this brief, and their letters of consent have been filed with the Clerk of this Court. Pursuant to Sup. Ct. R. 37(6), none of the parties or their counsel authored this brief in whole or in part. No person other than the LTCPA, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

of the nation's nursing home residents. The LTCPA members' pharmacies are very different than retail pharmacies; LTCPA members dispense drugs to nursing home residents and others in specialized "unit dose" packaging. As consultant pharmacists, they conduct patient drug regimen reviews, visit and consult with patients, and work with doctors to ensure that patients are prescribed optimal drug therapies. Because the majority of nursing home residents are Medicaid beneficiaries, LTCPA members are directly affected by restrictions placed on the dispensing of drugs under Medicaid programs such as those at issue here.

LTCPA members' ability to serve their Maine nursing home customers is directly and adversely affected by the Maine Rx Program. Subjecting Medicaid drugs to "prior authorization" to coerce drug manufacturers to participate in state rebate programs for the benefit of Maine residents will impede LTCPA members' ability to serve Maine Medicaid beneficiaries. The program also violates the letter, spirit, and Congressional intent of the Medicaid statute. The Court should scrutinize Maine's use of Medicaid's "prior authorization" provisions in terms of its impact on the quality of care provided to Medicaid beneficiaries.

SUMMARY OF ARGUMENT

One of the questions before the Court is whether the Maine Rx Program's prior authorization requirement is inconsistent with the Medicaid statute, thereby requiring the preemption of the Maine law. The underlying facts are not in dispute: Maine, through its "Maine Rx Program," will require prescription drug manufacturers to submit to a "rebate agreement" which will, in turn, allow the State to fund the reduction of drug prices for all Maine residents. The drugs of any manufacturer failing to participate in the "rebate" program will be placed on the state Medicaid program's "prior authorization" list, requiring doctors and/or

pharmacists to obtain specific state approval each time the drug is dispensed to a Medicaid beneficiary. Maine's sole purpose is to reduce the State's costs in subsidizing Maine citizens' prescription drug purchases, without regard to the effects of the program on Medicaid beneficiaries.

Amicus contends that the Maine Rx Program and State's ability to impose prior authorization requirements for the benefit of non-Medicaid patients is inconsistent with the Medicaid statute's text and underlying purpose. Specifically, the Maine Rx Program violates the Supremacy Clause because it imposes an obstacle to Congress' purpose in enacting the Medicaid Act. Arbitrarily subjecting drugs to prior authorization as Maine proposes will harm nursing home patients, the majority of whom are Medicaid beneficiaries, thus contravening the very purpose of the Medicaid statute.

Nursing home residents today are among the nation's most elderly and frail. Residents often require significantly more drug therapy than non-institutional Medicaid beneficiaries. Under the Maine Rx Program, however, doctors and long term care pharmacists will not have access to the prescription drugs that residents need. Thus, the nursing home residents will bear the brunt of the Maine Rx Program's arbitrary and illegal misuse of the prior authorization mechanism. While Maine may choose to subsidize its citizen's prescription drug purchases, it may not do so at the expense of Medicaid beneficiaries. Maine's prior authorization program must be consistent with the goals and objectives of the Medicaid Act. *Amicus*, thus, urges the Court to reverse the Court of Appeals' decision and to find that the Medicaid Act preempts the Maine Rx Program under the Supremacy Clause.

ARGUMENT

The Maine Rx Program on its face violates the Supremacy Clause by establishing prior authorization requirements that impose "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in the federal Medicaid Act. *See Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992) (quoting *Hines v. Davidowitz*, 312 U.S. 52 (1941)). Specifically, the Maine Rx Program's prior authorization requirement conflicts with the purpose of the federal Medicaid Act to provide health care to needy Americans. The Medicaid Act allows prior authorization programs, but not if such programs harm beneficiaries. The Maine Rx Program cannot be implemented without undermining "the full purposes and objectives of Congress" expressed in the Medicaid Act and its legislative history. *See Hines*, 312 U.S. at 67. Therefore, the Maine Rx Program's prior authorization requirements should be invalidated.

I. THE MAINE RX PROGRAM CONFLICTS WITH FEDERAL LAW BECAUSE IT WILL HARM THE FRAIL AND ELDERLY WHOM MEDICAID WAS CREATED TO SERVE.

In 1965, Congress enacted the federal Medicaid Act to allow States to provide "medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396.[2] Congress required participating states to

[2] The Centers for Medicare and Medicaid Services ("CMS," formerly "HCFA"), which oversees the Medicaid program, clearly notes this purpose in its regulations: "Title XIX of the Social Security Act, enacted in 1965, authorizes Federal grants to States for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children or qualified pregnant women or children." 42 C.F.R. § 430.0.

"provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients." 42 U.S.C. § 1396a(a)(19). The Maine Rx program's prior authorization requirement, however, will harm, rather than serve, the "best interests" of Medicaid recipients.

Recent studies document the cause and effect relationship between restrictive cost-containment programs (*e.g.*, formularies, prior authorization) and reductions in patients' access to drugs. *See, e.g.*, Neil J. MacKinnon & Ritu Kumar, *Prior Authorization Programs: A Critical Review of the Literature*, 7 J. Managed Care Pharmacy 297 (2001) (noting physicians' belief that prior authorization programs prevent patients from timely obtaining needed medications); Mental Health Assoc. in Mich. & Mich. Psychiatric Soc'y, *A Survey of Community Mental Health Services Programs Regarding Medications for Recipients Also Enrolled in Qualified Health Plans* (1999) (documenting providers' problems with prior authorization programs); Mark Schiller, *A Prescription for Medi-Cal*, Action Alert, Pacific Research Institute (1998) (concluding that the Medi-Cal drug treatment authorization request system prevents patients from obtaining "the most appropriate medications"); Stephen B. Soumerai *et al.*, *A Critical Analysis of Studies of State Drug Reimbursement Policies: Research in Need of Discipline*, 71 The Millbank Q. 217, 247 (1993) (citing study demonstrating decline in use of drug without substitute due to prior authorization requirement).[3]

[3] *See also* National Mental Health Association, *Penny-wise & Pound-Foolish: Restricting Access to Psychotropic Medications* (2002) (noting extensive paperwork associated with restricted medications can result in a loss of access of such medications to patients); The Lewin Group, *SAMHSA Managed Care Tracking System* 6 (1998) (finding mechanisms used to control access "may have negative consequences on consumer health status or overall behavioral health expenditures"); Henry G.

Prior authorization requires prescribing doctors (and/or dispensing pharmacists) to obtain specific state permission before dispensing drugs that are subject to the program. This additional procedural hurdle, appearing to some to be seemingly minor, in reality significantly impedes doctors' willingness to prescribe certain drugs. The Lewin Group, *SAMHSA Managed Care Tracking System* 6 (1998) (noting that the administrative requirements are "unduly burdensome"); Carl E. Hopkins *et al.*, *Cost-Sharing and Prior Authorization Effects on Medicaid Services in California: Part II: The Providers' Reactions*, 13 Med. Care 643 (1975) (documenting providers' feelings of harassment and inference from prior authorization requirements); *see also* Art Haymes, *Letters: Prior Authorization a Threat to Doctor-Patient Bond*, 90 Wis. Med. J. 506 (1991) (explaining disruptiveness of prior authorization programs on provider-patient relationship). Given the proliferation of paperwork that medical professionals must endure under today's managed care programs, doctors will switch drugs rather than endure the burden of obtaining authorization for a particular drug and waiting twenty-four hours before obtaining permission to prescribe a necessary medication. The result will be that patients will not get their doctor's "first choice" drugs simply because the manufacturer at some earlier point decided not to pay Maine a supplemental rebate for non-Medicaid purposes.

The adverse effects of Maine's prior authorization program will be borne principally by Maine's nursing home Medicaid

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Grabowski *et al.*, *The Effect of Medicaid Formularies on the Availability of New Drugs*, 1 (Supp. 1) PharmacoEconomics 32-40 (1992) (noting prior authorization creates strong incentives against prescribing drugs); Stephen B. Soumerai *et al.*, *Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*, 325 New Eng. J. Med. 1072 (1991) (documenting adverse impact of New Hampshire's cost-containment Medicaid requirement limiting the number of prescription drug reimbursements per month).

beneficiaries to whom LTCPA members dispense drugs. The average nursing home patient is 83.1 years old [4] and requires six prescription medications (with forty-five percent requiring seven and twenty percent needing ten or more drugs). The numbers of prescriptions are not due to over-medication, but, rather, are necessary because of nursing home residents' poorer health as compared with that of ambulatory seniors living at home or in assisted living facilities.[5] Studies indicate that nursing home patients have multiple medical conditions, often accompanied by impaired or abnormal cognitive function.[6] These residents' serious medical conditions make unobstructed access to the appropriate medications critical. Mark Monane *et al.*, *Pharmacotherapy: Strategies to Control Drug Costs in Managed Care*, 53

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[4] Roberto Bernabei *et al.*, *Characteristics of the SAGE Database: A New Resource for Research on Outcomes in Long-term Care*, 54 J. Gerontology: Med. Sci. M25 (1999). Sixty-six percent of those entering nursing homes are already on Medicaid, and those residents who are not eligible upon admission are very likely to become Medicaid eligible (through the process known as "spending down") within their first year of residing in a skilled nursing facility.

[5] J. Lyle Bootman *et al.*, *The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities*, 157 Archives of Internal Med. 2089 (1997).

[6] A recent HCFA-sponsored analysis suggests that nursing home patients have on average 7.8 medical conditions. *See* Thomas Bodenheimer, *Long Term Care for Elderly People, The On-Lok Model*, 341 New Eng. J. Med. 1324, 1326 (1999) (analyzing 1995 data indicating average patient was eighty years old, has 7.8 medical conditions, and had impairments impeding performance of two to three activities of daily living). In addition, changes in bodily function capacity mean that the elderly process prescriptions different than younger patients. As a result, the elderly require specific geriatric formularies. *See* Mark Monane *et al.*, *Pharmacotherapy: Strategies to Control Drug Costs in Managed Care*, 53 Geriatrics 51 (1998). Understanding the specifics of geriatric care and ensuring that the right drugs are available to be dispensed are critical to providing appropriate treatment and avoiding inappropriate medication interaction.

Geriatrics 51 (1998) (finding that cost-containment strategies must be adopted with care because many elderly patients have multiple diseases that require physicians to maximize the appropriate use of drugs, while avoiding duplicative or interacting medications). The advanced medicines now available permit significant improvements in quality of life to long term care residents who previously had little hope of recuperation from serious illnesses.

The Maine Rx Program's prior authorization requirement, however, will have the practical effect of preventing long term care pharmacies from dispensing the necessary drugs to nursing home residents. Pharmacies forced to dispense a second choice drug will find it difficult, if not impossible in certain instances to find a medication that treats the patient effectively, avoids dangerous side effects, and does not interact inappropriately with a patient's other medications.[7] No matter how noble Maine's motivation in enacting the Maine Rx Program might be, imposing prior authorization on the drugs of certain manufacturers for reasons unrelated to treatment will harm the interests of Maine Medicaid patients in violation of statute and Congress's purposes and objectives in enacting the Medicaid program.

In sum, subjecting drugs to prior authorization only because the manufacturer is unwilling to engage in a separate

[7] Avoiding inappropriate drug interactions and medication errors is particularly important for nursing home residents. *See* Bootman, *supra*, at 2089 (positively correlating number of prescriptions and increased risk of medication errors and estimating that every dollar spent on prescription drugs generates an additional cost of $ 1.33 in health care costs associated with medication errors). Dr. Bootman was able to estimate that consultant pharmacist intervention saved the health care system $3.6 billion (in 1997 dollars) by avoiding drug related problems. Maine's prior authorization scheme, however, will hinder consultant pharmacists' ability to prevent medication errors through drug substitution, which ironically will lead to greater, rather than lower, Maine health care costs.

state rebate program for non-Medicaid patients is not in the best interests of Medicaid nursing home residents. The real-world effect will be to limit access to drugs based upon financial concerns for non-Medicaid patients, rather than based upon the medical and health requirements of Medicaid patients.[8] Ultimately, the Maine Rx Program will have the unintended consequence of preventing LTCPA members from dispensing those medically necessary drugs to the patients who need them most—nursing home Medicaid beneficiaries.

II. THE MAINE RX PROGRAM CONTRADICTS MEDICAID'S GOAL OF BENEFITING A TARGETED POPULATION.

The Maine Rx Program's misuse of Medicaid's prior authorization program also is inconsistent with the Medicaid Act as a whole. Medicaid is intended to serve needy individuals, not *all* individuals. In contrast, the Maine Rx Program targets *all* individuals within Maine purchasing prescription drugs—both rich and poor. *See* Me. Rev. Stat. Ann. tit. 22, §2681. The Maine legislature enacted the Maine Rx Program "to make prescription drugs more affordable for qualified[9] Maine residents, thereby increasing the overall

[8] Maine has argued below that the provision is not inconsistent because it authorizes the use of prior authorizations only "as permitted by law." Me. Rev. Stat. Ann. tit. 22, § 2681(7). However, for Maine's statutory provision to have some meaning, as it must, at least some drugs will be subject to prior authorization on the basis of manufacturer identity, rather than medical necessity. What Maine ignores is the reality that different drugs have different effects on different people and that it is the doctor's prescription, in conjunction with the consultant pharmacist's review and consultation, that the law dictates must guide the dispensing of drugs to Medicaid beneficiaries.

[9] A "qualified resident" is "a resident of the State who has obtained from the department a Maine Rx enrollment card." Me. Rev. Stat. Ann. tit. 22, § 2681(2)(F) (footnote added).

health of Maine residents, promoting healthy communities and protecting the public health and welfare." *Id.* at § 2681(1). While perhaps serving an important state purpose, this law, as the Solicitor General has noted, has "no Medicaid purpose [that] appears to be served by a state program focusing on that population." Brief for the United States as *Amicus Curiae* at 13.

The Maine statute's conflict with the Medicaid Act's purpose creates an obstacle to achieving the federal goal of providing health care to needy individuals. By adopting programs that benefit non-Medicaid beneficiaries, Maine has diverted valuable resources that inevitably will harm the population Medicaid is intended to protect.

III. THE MAINE RX PROGRAM ALSO CONFLICTS WITH MEDICAID'S EQUAL ACCESS REQUIREMENT.

The Maine Rx Program's prior authorization provision also conflicts with 42 U.S.C. § 1396a(a)(30)(A), the Medicaid Act's equal access provision. That provision requires that Maine's Medicaid program be implemented to "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." Federal courts analyzing the requirement have concluded that under this provision "budgetary considerations cannot be the conclusive factor in decisions regarding Medicaid." *Arkansas Med. Soc'y v. Reynolds*, 6 F.3d 519, 531 (8th Cir. 1993); *see also Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491, 1500 n.3 (9th Cir. 1997) (rejecting Medicaid changes made "for purely budgetary reasons"); *Ohio Hosp. Ass'n v. Ohio Dep't of Human Servs.*, 579 N.E.2d 695, 698 (Ohio 1991) (same); *cf. Methodist Hosps. v. Sullivan*, 91 F.3d 1026, 1030 (7th Cir. 1996). Yet, the Maine Rx Program modifies the Medicaid requirements for precisely such budgetary reasons.

The inevitable result of the Maine statute is to create a conflict with the federal Medicaid Act's mandate to provide efficient, economical and a high level of health care to needy individuals. Maine Medicaid participants will be denied the access to drugs enjoyed by the general population, because doctors will avoid prescribing drugs on the prior authorization list. Hijacking the prior authorization process in the name of lowering the costs of prescription drugs for other Maine residents violates both the Medicaid statute's purpose and text.

IV. THE MAINE RX PROGRAM VIOLATES CONGRESS'S INTENT IN PERMITTING PRIOR AUTHORIZATION.

The Maine Rx Program's prior authorization provisions also conflict with the conditions under which Congress created prior authorization. The Medicaid Act permits prior authorization only if the state also provides: (1) a response to authorization requests within twenty-four hours; and (2) the dispensing of a seventy-two-hour supply of the covered drug in emergency situations. 42 U.S.C. § 1396r-8(d)(5)(A) & (B). Although the relevant statutory provisions do not explicitly speak to *when* states may use prior authorization,[10] Congress's intent is expressed in the Conference Report

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[10]The First Circuit misread the Act to allow a prior authorization for "any" purpose, because the prior authorization provision applies to "any" drug. *See* 42 U.S.C. § 1396r-8(d)(5)(A); *Pharmaceutical Research & Manuf. of America v. Concannon*, 249 F.3d 66, 76 (1st Cir. 2001); *see also Pharmaceutical Research & Manuf. of America v. Meadows*, --- F.3d ---, 2002 WL 31000606 *9 (11th Cir. September 6, 2002) (using same rationale). Permission to apply prior authorization to "any drug," however, hardly supports allowing the program for "any purpose." Thus, reference to legislative history is necessary. *See Barnhill v. Johnson*, 503 U.S. 393,402 (1992) (noting appropriateness of using legislative history when statute's intent is unclear).

which explains that: "the option of imposing prior authorization requirements with respect to covered prescription drugs [is] in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." H.R. Rep. No. 881, 101st Cong., 2d Sess. 98 (1990).[11] The Maine Rx Program, however, is indifferent to the efficiency and economy of the Medicaid program and presents a serious threat to the "quality of care" Maine currently provides to Medicaid beneficiaries. Thus, Maine's use of prior authorization as a lever to extract lower prices for non-Medicaid populations is directly contrary to Congress's intent.

Congress's goals of avoiding over-utilization and assuring appropriate treatment are, of course, consistent with the Medicaid Act itself. The legislative history mirrors the requirements of 42 U.S.C. § 1396a(a)(30)(a) ("efficiency, economy, and quality of care"). States may, thus, only use prior authorization for purposes consistent with these criteria. The Maine Rx Program's use of prior authorization, however, directly conflicts with them.

CONCLUSION

The Maine Rx program violates the overall purpose of the Medicaid Act, Congress's intent in allowing prior authorization programs, and the best interests of Medicaid beneficiaries. Prior authorization requirements have a devastating impact on the care of Medicaid beneficiaries, many of whom are nursing home residents. Congress provided for limited use of prior authorization programs, and then only to address the equally harmful problem of improper drug utilization.

The Maine Rx Program does not employ prior authorization to protect Medicaid beneficiaries from over-utilization

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[11] For example, it may be appropriate for States to subject Oxycontin, a pain medication widely recognized as being abused, to prior authorization.

or to improve the efficiency, economy, or quality of care. Instead it adopts prior authorization as a means of forcing pharmaceutical manufacturers into submitting to supplemental state rebates. Maine's purpose conflicts with Congressional intent as expressed in Medicaid's statutory requirements and its legislative history. Therefore, it violates the Supremacy Clause and must be found unconstitutional. The First Circuit's decision should be reversed.

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KEVIN CONCANNON, Commissioner, Maine Department of Human Services, and G. STEVEN ROWE, Attorney General of Maine,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF OF THE INTERNATIONAL PATIENT ADVOCACY ASSOCIATION, NATIONAL ALLIANCE FOR THE MENTALLY ILL - MICHIGAN, AND CALVIN P. FUHRMANN, M.D. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE*

Amici Curiae International Patient Advocacy Association and National Alliance for the Mentally Ill-Michigan represent beneficiaries of various state Medicaid entitlement programs funded and operated under federal law requirements. *Amicus curiae* Calvin P. Fuhrmann, M.D. is a physician practicing in Maine who treats Medicaid beneficiaries. *Amici* have a strong interest in this Court reversing the judgment below and enjoining the Maine Rx program to safeguard the benefits accorded to Medicaid beneficiaries by federal law.[1]

In 1990 and 1993, Congress amended the Medicaid program to give states the benefit of a federally established "best price" for prescription drugs and to ensure *amici* beneficiaries (and those providing medical care to them), the same access to those drugs as non-Medicaid patients, subject only to narrow and carefully crafted exceptions. If Maine and other states are permitted to impose burdensome prior authorization requirements on "best price" prescription drugs because their manufacturers refuse to accede to state demands unrelated to Medicaid, Medicaid beneficiaries will suffer. This litigation, and the other litigation pending in state and federal trial and appellate courts throughout the United States, makes it all too evident that the Maine Rx program, and others of its ilk, will not produce manufacturer acquiescence, at least until prescription drug use by Medicaid beneficiaries is ratcheted down sufficiently to make payment of non-Medicaid demands less onerous to manufacturers than the

1. Pursuant to Sup. Ct. Rule 37, the written consents of the parties to the filing of this brief have been filed with the Clerk. Counsel for the parties did not author this brief, in whole or in part, and no one other than the *amici curiae*, their members, and counsel made a monetary contribution to the preparation of this brief.

loss of Medicaid sales. Thus, Medicaid beneficiaries, contrary to their health interests and the protections afforded them by federal law, will be made the lever through which states seek to achieve non-Medicaid ends.

Amicus International Patient Advocacy Association ("IPAA") is a United States-based non-profit organization dedicated to patient advocacy both domestically and abroad. Through a network of volunteers, IPAA provides extensive support and assistance to patients throughout the United States and in several other countries. IPAA focuses in particular on meeting the needs of those with chronic illnesses or rare genetic disorders. Individual patients receive various forms of assistance, including aid in obtaining medical information, as well as in securing treatment and insurance coverage, access to legal resources, and participation in forums attended by members of the medical community. IPAA also serves patients' interests on a broader scale by advocating vigorously for patients' rights before state legislatures and Congress. In furthering its goals, IPAA works closely with physicians, medical industry representatives, and legislators. Because of its strong interest in protecting Medicaid beneficiaries, and in other Medicaid-related issues, IPAA also recently appeared as an *amicus* in a pending case challenging a program in Michigan similar to Maine Rx.

Amicus National Alliance for the Mentally Ill-Michigan ("NAMI-Michigan") was founded by families of individuals suffering from severe mental illness. The families served by NAMI-Michigan include those of Michigan residents who are diagnosed with major mental illnesses, including schizophrenia, bipolar disorder, major depressive disorder, and schizoaffective disorder. These individuals typically are very fragile and in need of lifelong medical assistance. Many

rely on Medicaid to provide access to prescription drugs. Changes in their drug regimen for any reason other than medical necessity can have dire consequences for them. NAMI-Michigan recently was granted leave to appear as an intervenor in the case now pending in the U.S. District Court for the District of Columbia concerning the Michigan program.

Amicus Dr. Calvin P. Fuhrmann is the Medical Director of the Kennebunk Medical Center in Kennebunk, Maine. The Kennebunk Medical Center is a busy primary care facility, and its two doctors and one nurse practitioner serve a diverse community – from the poorest of the poor to members of the President's family. The center treats an average of 50 patients per day, a number of whom are Medicaid recipients. Dr. Fuhrmann has personally experienced the added red tape and difficulties that prior authorization requirements impose on his staff and his patients. Very often, Dr. Fuhrmann chooses to prescribe what otherwise would be his second-choice drug to avoid prior authorization difficulties for himself and his patients. Dr. Fuhrmann believes that his Medicaid patients should not be denied access to the best medications for them merely so that other patients, who can afford to purchase prescription drugs outright, can obtain a discount through Maine Rx.

The Medicaid beneficiaries represented and cared for by *amici* are among those Americans least able to cope with administrative complexity or to assert their rights against state-created obstacles. Maine's interests in exerting economic leverage against pharmaceutical companies and in reducing the cost of its Medicaid drug benefit may be served by denying these Medicaid beneficiaries access to drugs they need, but beneficiaries' congressionally protected interests are not. Maine Rx will strike these beneficiaries at the

pharmacy level, when pharmacists are forced to demand full payment for prescriptions rather than a nominal Medicaid co-pay. Many beneficiaries will simply abandon the pursuit of necessary medication and accept the adverse health consequences. *Amici* prevail upon this Court to uphold the letter and spirit of the Medicaid laws and avoid this unacceptable result.

FACTUAL AND LEGAL BACKGROUND

A. Relevant Medicaid Provisions

The principal objective of the Medicaid program is "to furnish . . . medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services. . . ." 42 U.S.C. § 1396. Although Medicaid is administered by the states, Congress has imposed strict requirements on states for the protection of Medicaid beneficiaries. Each state must prepare a "Medicaid State Plan" in accordance with the statutory requirements set out in 42 U.S.C. § 1396a. The Act mandates that each state plan "provide such *safeguards as may be necessary to assure that . . . care and services will be provided, in a manner consistent with* simplicity of administration and *the best interests of [Medicaid] recipients.*" 42 U.S.C. § 1396a(a)(19) (emphasis added).

In order to protect vulnerable beneficiaries, Congress has enacted detailed legislation concerning the prescription drug benefits that states make available through Medicaid.[2] Prior

2. The Social Security Act, which governs Medicaid, does not mandate provision of a prescription drug benefit through Medicaid. However, as discussed below, the Act does establish strict and detailed requirements if such a benefit is conferred.

to the passage of OBRA-90, Medicaid drug prices were established at the state level, and some states used price-based "formularies" — restricted lists of covered drugs — to contain prescription drug expenditures. Congress explicitly recognized that this practice constrained Medicaid recipients' ability to obtain access to the drugs their doctors believed would be most effective for them but also recognized the need to husband limited state resources. To further the dual aims of broadening patient access to prescription medications and containing costs, Congress in 1990 established the Federal Medicaid Rebate Program as part of the Omnibus Budget Reconciliation Act of 1990 ("OBRA-90").[3] OBRA-90 abolished state formularies that excluded drugs from coverage for economic reasons and created a federal rebate program giving all state Medicaid programs the advantage of "best price" purchasing. This program entitled Medicaid beneficiaries to access all prescription drugs whose manufacturers agreed to provide federal "best price" rebates.[4] As stated in the related House Report,

> [b]ecause the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription drugs

3. 42 U.S.C. § 1396a(a)(54), *added by* Pub. L. No. 101-508, § 4401(a)(2)(C), 104 Stat. 1388 (1990); *see also* H.R. Rep. No. 101-881, at 96-97 (1990) ("OBRA-90 House Report"), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108-09 (describing preexisting law).

4. 42 U.S.C. § 1396b(i)(10), *added by* Pub. L. No. 101-508, § 4401(a)(1)(B), 104 Stat. 1388 (1990); *see also* OBRA-90 House Report, at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110.

> to cover all of the products of any manufacturer that agrees to provide price rebates.

H.R. Rep. No. 101-881, at 96-97 (1990) ("OBRA-90 House Report"), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108-09.

While OBRA-90 forbade states from excluding coverage of drugs for which manufacturers provided "best price" rebates, it did not leave states powerless to avoid needless or wasteful expenditures. Congress explicitly permitted states to impose limitations "on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste." 42 U.S.C. § 1396r-8(d)(6). Congress also allowed states to "subject to prior authorization any covered outpatient drug" so long as that categorization was consistent with the need for "efficiency, economy and quality of care." 42 U.S.C. § 1396r-8(d)(1)(A).[5] Prior authorization programs also were required to respond to authorization requests within 24 hours and to provide at least a 72-hour supply of the drug in an emergency without prior approval. 42 U.S.C. § 1396r-8(d)(5).

In 1993, Congress once again adjusted the "delicate balance between cutting program costs, improving the access of Medicaid patients to needed medicines, and preserving the incentives necessary to encourage continued pharmaceutical research and development." 136 Cong. Rec. 51579-02, 515859 (daily ed. Oct. 18, 1990), 1990 WL 158480 (statement of Sen. Hatch). In the Omnibus Budget Reconciliation Act of 1993 ("OBRA-93"), Pub. L. No. 103-

5. *See* OBRA-90 House Report at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110 (primary purpose of prior authorization is to assure that Medicaid payments for prescription drugs are "consistent with efficiency, economy and quality of care").

66, 107 Stat. 312, 616-17 (1993), Congress restored the authority of states to develop comprehensive formularies of preferred drugs but sharply limited their ability to exclude from those formularies the drugs of manufacturers that had entered into federal rebate agreements. Such drugs could be restricted on states' formularies

> only if . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

42 U.S.C. § 1396r-8(d)(4)(C).[6]

OBRA-93, which remains in effect, also redefined the concept of formulary for Medicaid purposes by eliminating exclusions from Medicaid coverage. Congress specifically required that every drug excluded from a (d)(4) formulary be available through a Medicaid-compliant prior authorization program. 42 U.S.C. § 1396r-8(d)(4)(D). Thus, Congress in OBRA-93 reaffirmed the basic commitment, first made in OBRA-90, that Medicaid beneficiaries would not be denied access to "best price" prescription drugs for non-clinical reasons.

As presently delineated in the Social Security Act ("the Act"), there are only three categories of drugs excluded from the requirement that Medicaid beneficiaries have access to all drugs manufactured by companies that have signed rebate

6. As a further protection, "Manufacturers could obtain judicial review of a decision to exclude a drug from a formulary." H.R. Rep. No. 103-111, at 205 (1993) ("OBRA-93 House Report"), *reprinted in* 1993 U.S.C.C.A.N. 378, 532.

agreements. *See* 42 U.S.C. § 1396r-8(d) (listing "[l]imitations on coverage of drugs"). First, states may "exclude or otherwise restrict coverage" of any drug when "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).[7] Second, states may exclude certain categories of drugs that treat conditions deemed not sufficiently weighty to warrant Medicaid coverage, as well as drugs "subject to clinical abuse or inappropriate use." *See* 42 U.S.C. § 1396r-8(d)(2)-(3). Thus, for example, Congress did not require states to cover drugs intended to treat hair loss or provide symptomatic relief of coughs and colds, nor are the states required to cover barbituates. *See* 42 U.S.C. § 1396r-8(d)(2).

The third (and final) category through which states may restrict coverage of prescription drugs is through a formulary conforming to Section 1396r-8(d)(4). The formulary provision, unlike the more particularized exclusions in subsections (d)(1)(B) and (d)(2), contemplates systemic review of covered prescription drugs. However, the formulary provision added by OBRA-93 did not return to the pre-OBRA-90 exercise of discretionary, cost-based exclusion. Instead, Congress established a number of strict limits on states' abilities to create formularies. First, the formulary must be developed by a committee of physicians, pharmacists, or other qualified individuals (Subsection (d)(4)(A)). Second, the formulary must include all of a manufacturer's drugs if that manufacturer has agreed to provide a rebate (subsection (d)(4)(B)). States may only exclude a participating manufacturer's drug "with respect to the treatment of a specific disease or condition for an identified population" and only if they determine that it "does not have a significant, clinically meaningful therapeutic advantage" over other drugs included in the formulary. Even then, the decision

7. 42 U.S.C. § 1396r-8(d)(1)(B) also includes cross-references to subsections (d)(2) and (d)(4), which are discussed below.

must be supported by a "written explanation (available to the public) of the basis for the exclusion" (subsection (d)(4)(C)). Emphasizing the seriousness of dropping a drug into prior authorization by exclusion, this latter requirement was designed to permit judicial review. *See* H.R. Rep. No. 103-111, at 205 (1993) ("OBRA-93 House Report"), *reprinted in* 1993 U.S.C.C.A.N. 378, 532 ("[m]anufacturers could obtain judicial review of a decision to exclude a drug from a formulary").

The totality of the regime established by OBRA-90 and OBRA-93 thus establishes Congress' intent to protect beneficiaries' access to needed prescription drugs so long as the manufacturers of those drugs accept the federal rebate program.

B. The Maine Rx Program

Contrary to the requirements of the OBRAs, the Maine Rx program is intended to limit Medicaid beneficiaries' access to prescription drugs manufactured by companies that have agreed to provide federally-mandated rebates. Under Maine Rx, manufacturers whose drugs are sold in Maine are required to enter a separate rebate agreement with the state covering all drugs sold to participating Maine residents outside the Medicaid program. Me. Rev. Stat. Ann. tit. 22, § 2681(3) (West 2001). Participation in Maine Rx is open to all state residents; the rebate obligation (which is paid to the state, as in Medicaid) is triggered by a sale to any program enrollee. *Id.* Although the amount of the rebate theoretically is subject to negotiation, the Commissioner is instructed to use his "best efforts" to obtain the same rebate as provided for Medicaid sales. *Id.* § 2681(4)(C). If a manufacturer refuses

to pay the demanded rebate, its products are put into prior authorization status under Maine's Medicaid program, thereby pressuring the manufacturer to comply by sharply limiting beneficiaries' access to needed prescription drugs. *Id.* § 2681(7).

C. Impact of Maine Rx and Similar Programs on Beneficiaries and Providers

With Maine Rx in place, a Medicaid beneficiary could obtain a prescription for a medication she has been taking for years, including a prescription necessary to treat a serious or debilitating disease, only to have that prescription rejected for Medicaid reimbursement at the pharmacy. In this situation, the recipient's only recourse would be to (1) have her doctor prescribe a second-choice drug, if the doctor could be reached and any such drug were available, (2) have the doctor seek prior authorization (if the doctor were reachable and willing to invest the time necessary to do so), (3) pay for the entire prescription out-of-pocket herself, rather than the statutorily required "nominal" Medicaid co-payment,[8] or (4) forego altogether the prescribed drug or any substitute. A mix of these outcomes is likely and the magnitude of harm to Medicaid beneficiaries may vary in each individual situation from a minor inconvenience to a potential health emergency. In no case, however, is there any corresponding benefit to Medicaid beneficiaries. Moreover, the benefits sought by Maine lie entirely outside the Medicaid program.

If experiences in other jurisdictions are any guide, the scenarios outlined above will be widespread as soon as Maine Rx goes into effect. In Michigan, for example, the state recently implemented a non-Medicaid rebate agreement

8. 42 U.S.C. § 1396o(b)(3).

using the threat of Medicaid prior authorization as leverage. Most manufacturers refused to comply, thereby converting to prior authorization status hundreds of prescription drugs that had been readily available to Medicaid patients. *See Pharmaceutical Research & Manufacturers of America v. Thompson*, No. 02-CV-1306 (JDB) (D.D.C. filed June 28, 2002) (challenging federal approval of the Michigan Pharmaceutical Best Practices Initiative). No different outcome can be anticipated in Maine, particularly in view of the unrestricted nature of the Maine Rx program. Thus, Maine Rx will inflict immediate and potentially irreparable medical harm on Medicaid beneficiaries in Maine. Numerous other states already are enacting similar plans. Thus, if this Court does not reverse the decision below, similar harm soon will be visited upon Medicaid beneficiaries nationwide.

It is no answer to point to the possibility of obtaining prior authorization. Because of the numerous and varying lists of approved drugs (insurance companies, HMOs, Maine Rx, etc.), physicians cannot be expected to know, and often do not know, what drugs are approved without prior authorization for any given patient. The reality, therefore, is that numerous prescriptions for Medicaid beneficiaries will be written for drugs that are subject to prior authorization. This will be discovered by the beneficiary only when she arrives at the pharmacy to have her prescription filled. While this scenario is problematic for anyone, it is particularly problematic for indigent and/or disabled Medicaid beneficiaries, many of whom lack the capability and resources to pursue authorization diligently and overcome the inevitable (and intended) roadblocks. Moreover, Maine has every intention of declining prior authorization even when it is requested. As the First Circuit noted, "[t]he state concedes that it will not authorize payment for the first-choice drug

manufactured by a non-participant where there is another drug for the ailment manufactured by a participant." *Pharmaceutical Research & Mfrs. of America v. Concannon*, 249 F.3d 66, 77 (1st Cir. 2001). Indeed, Maine Rx's leveraging depends for its success on diminution of sales by manufacturers that decline to enter Maine Rx agreements.

Physicians who care for Medicaid beneficiaries, like *amicus* Dr. Fuhrmann, also will be harmed if Maine Rx is permitted to take effect. His patients, for whose care he is responsible, may be denied access to the prescription drugs that Dr. Fuhrmann determines in his professional judgment are best suited for them. Dr. Fuhrmann also will be compelled to divert attention from patient care in order to attempt to secure prior authorization. In the alternative, he can prescribe what could otherwise be a second-choice medication. Significantly, these would not be generic equivalents (determined to be pharmaceutically equivalent by FDA), but different chemical compounds altogether, which may have different dosing regimens, contraindications, and side effects. Thus, Dr. Fuhrmann's ability to treat his patients as effectively will be compromised if Maine Rx takes effect.

SUMMARY OF ARGUMENT

This case presents a question that is now of national import to Medicaid beneficiaries: whether federal law permits states to restrict the access of Medicaid beneficiaries to needed, "best priced" prescription drugs in order to serve non-Medicaid budgetary interests. Continuing judicial validation of the Maine scheme at issue would upset a carefully balanced structure established by Congress in 1990 and 1993, when it required (except in narrowly defined circumstances not applicable here) that the drug benefit in

state Medicaid programs provide beneficiaries access to all prescription drugs manufactured by companies that agree to pay rebates established by act of Congress.

Further, because Medicaid beneficiaries' access to necessary prescription drugs is being restricted in order to achieve non-Medicaid goals, the Maine Rx program is directly contrary to the "best interests" of Medicaid recipients and is therefore unlawful under the Social Security Act. Maine and the many other states poised to follow it should not be permitted to use the "prior authorization" provisions of the Act — which were intended to serve Medicaid purposes and apply only in limited circumstances — to pursue non-Medicaid state goals by putting at risk the ability of Medicaid beneficiaries to obtain the drugs that their physicians believe are best for them. Thus, the decision of the court of appeals should be set aside and the preliminary injunction entered by the district court reinstated.

ARGUMENT

I. MAINE RX CREATES AN UNLAWFUL DE FACTO MEDICAID FORMULARY THAT RESTRICTS MEDICAID BENEFICIARIES' ACCESS TO COVERED OUTPATIENT DRUGS CONTRARY TO STATUTORY REQUIREMENTS.

The Supremacy Clause, U.S. Const. art. VI, cl. 2, invalidates state laws that "interfere with, or are contrary to," federal law. *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824). "Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law." *Hillsborough County, Fla. v. Automated Med. Labs.*,

Inc., 471 U.S. 707, 713 (1985). Here, Maine Rx violates the protections established in the Act for Medicaid beneficiaries and is therefore unlawful.

As set out above, a core principle of the Act, post-OBRA-90 and OBRA-93, insofar as it pertains to prescription drugs, is that Medicaid beneficiaries will have unfettered access to all drugs whose manufacturers have agreed to pay the federally established Medicaid rebate. As stated in the House Committee report accompanying OBRA-90: "States that elect to offer prescription drug coverage under their Medicaid programs *would be required to cover all of the drugs of any manufacturers entering into and complying with such an agreement with the Secretary*." OBRA-90 House Report, at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110 (emphasis added). This trade-off — rebates for full and freely available coverage — is reflected in the statute. Consistent with prior practice, the new provisions included language directed at preventing waste, fraud, and abuse (*e.g.*, 42 U.S.C. § 1396r-8(d)(6), limiting quantities and refills), and reflected the judgment that certain conditions (*e.g.*, baldness, per *id.* (d)(2)(C)) were not worthy of coverage, but did not permit states on a more global basis to decline to cover drugs whose manufacturers had entered federal rebate agreements.[9]

OBRA-93 altered OBRA-90 to some degree, but not in a way that would save Maine Rx. OBRA-93 resurrected state formularies, which placed certain "best price" drugs in prior authorization status for clinical reasons subject to strict requirements for Medicaid beneficiary protection that Maine Rx does not meet. Subsection (d)(4)(C) provides:

9. The prior authorization provision in 42 U.S.C. § 1396r-8(d)(1)(A) relied upon by the First Circuit does not affect this conclusion, for the reasons discussed in Part II, *infra*.

> A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

42 U.S.C. § 1396r-8(d)(4)(C). The Maine Rx program has no such clinical component, however, let alone an exclusive focus on clinical factors. *See* Me. Rev. Stat. Ann. tit. 22, § 2681 (West 2001). Rather, its exclusion criterion is a *non-Medicaid economic factor*, namely failure to acquiesce to the non-Medicaid rebate demanded by the state. This linkage is unlawful even in the view of courts that have taken a broad view of prior authorization authority. As the Eleventh Circuit recently concluded, exclusion from a (d)(4) formulary "must be based solely on clinical factors." *Pharmaceutical Research & Mfrs. of America v. Meadows*, No. 02-10151, 2002 WL 31000006, at *9 (11th Cir. Sept. 6, 2002).[10]

While Maine has claimed that it will establish a committee to review exclusion determinations, the unmistakable import of the Maine Rx statute is that drugs are to be placed in prior authorization status (*i.e.*, excluded

10. In the view of the undersigned *amici*, the Eleventh Circuit erred by, among other things, reading the prior authorization provision in 42 U.S.C. § 1396r-8(d)(1)(A) so broadly as to eviscerate the formulary provision of 42 U.S.C. § 1396r-8(d)(4). The case is discussed in Part II, *infra*.

from the formulary) based on a single economic factor — the presence or absence of a non-Medicaid rebate agreement — rather than the precise, detailed therapeutic factors that Congress has required in subsection (d)(4)(C). *See* 42 U.S.C. § 1396r-8(d)(4)(C). In addition, Maine Rx makes no provision for the public, judicially reviewable exclusion findings that Congress contemplated. *See* OBRA-93 House Report, at 205, *reprinted in* 1993 U.S.C.C.A.N. at 532. Maine Rx contemplates an essentially binary, unreviewable decision as to whether the manufacturer has acceded to the non-Medicaid rebate demanded by the state in order to develop a comprehensive list of automatically approved and prior authorization drugs. As such, Maine Rx constitutes an unlawful, *de facto* formulary that violates the requirements of the Act.[11]

II. PRIOR AUTHORIZATION AUTHORITY UNDER MEDICAID CANNOT BE CONSTRUED TO EVISCERATE THE FUNDAMENTAL BALANCE OF THE ACT, INCLUDING THE PROTECTION OF BENEFICIARY ACCESS TO PRESCRIPTION DRUGS.

Maine has defended the Maine Rx program on the ground, accepted by the First Circuit, that essentially anything goes when it comes to Medicaid prior authorization

11. Maine has acted unilaterally against the interest of Medicaid recipients, without even officially altering its Medicaid state plan or obtaining the requisite federal approval. *See* 42 C.F.R. § 430.12(c)(ii) (State plan amendment must be submitted "whenever necessary to reflect . . . [m]aterial changes in State law, organization, or policy, or in the State's operation of the Medicaid program"). Forcing most prescription drugs into prior authorization status surely qualifies as a "material change[ ] . . . in the State's operation of the Medicaid program." *Id.*

requirements. In substance, Maine contends, taking the language of 42 U.S.C. § 1396r-8(d)(1) in isolation, that it can impose any prior authorization requirements that it wishes, for any reasons that it wishes, so long as it complies with the 24-hour response/72-hour emergency supply provision in 42 U.S.C. § 1396r-8(d)(5). The First Circuit agreed. *See PhRMA v. Concannon*, 249 F.3d at 76-77.

Maine's reading cannot be reconciled with the overall structure of the Act or its intended purpose. Acceptance of Maine's position would both upset the overall balance created by Congress in OBRA-90 and OBRA-93 and vitiate the detailed formulary provisions added in OBRA-93. Such an outcome cannot withstand scrutiny. *Reves v. Ernst & Young*, 494 U.S. 56, 63 (1990) ("the phrase 'any note' should not be interpreted to mean literally 'any note,' but must be understood against the backdrop of *what Congress was attempting to accomplish*" (emphasis added)). "Statutory construction . . . is a holistic endeavor." *United Savings Ass'n v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988). Broad statutory provisions must be read in context, because often "only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law." *Id.* (citations omitted).

As discussed above, the fundamental bargain reflected in the OBRAs was full beneficiary access in return for manufacturer rebates. *See* OBRA-90 House Report, at 95-98, *reprinted in* 1990 U.S.C.C.A.N. at 2107-10. Prior authorization, which originally was intended to prevent waste, fraud, and abuse in particularized circumstances, was not intended to give the states authority to develop a comprehensive, back-door formulary which would circumvent this balance carefully set by Congress:

As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care. However, the *Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements — i.e., assuring access by Medical beneficiaries to prescription drugs where medically necessary.*

OBRA-90 House Report, at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110 (emphasis added).

The detailed formulary provisions added by Congress in OBRA-93 confirm this view. Under the OBRA-93 provision, formularies cannot totally exclude drugs whose manufacturers have signed national "best price" agreements, unless these drugs are not of a type otherwise subject to exclusion under (d)(1)(B) or (d)(2). Rather, "exclusion" of a drug from a formulary is limited to placing that drug in prior authorization status. *See* 42 U.S.C. § 1396r-8(d)(4)(D) (one formulary requirement is that "[t]he state plan permits coverage of a drug excluded from the formulary . . . pursuant to a prior authorization program").[12]

12. The Eleventh Circuit, in dealing with a Florida program that did not include non-Medicaid rebate criteria, read the 42 U.S.C. § 1396r-8(d)(4) formulary provision as permitting complete exclusion (Cont'd)

If Maine's view were correct — that subsection (d)(1)(A) provided an unlimited right to impose prior authorization — the subsequently enacted formulary provision in subsection (d)(4) would be meaningless, because no state would ever comply with its strictures (plus subject formulary decisions to judicial review) when exactly the same result could be reached under the pre-existing subsection (d)(1) without the need for a committee, without the need for a substantive standard, without the need for a reasoned decision, and without the possibility of judicial review. It is well-established that statutes should not be interpreted so as to render parts of them meaningless. *Astoria Fed. Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991) (courts should construe statutes "to avoid rendering superfluous any parts thereof"); *United States v. Menasche*, 348 U.S. 528, 538-539, (1955) (court has a "duty to give effect, if possible, to every clause and word of a statute" (quoting *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883)). That is exactly the result that would obtain were the Court to accept Maine's

(Cont'd)
of coverage of a drug, as opposed to a mere prior authorization requirement. *See Meadows*, 2002 WL 31000006, at *9. In fact, however, Congress unequivocally precluded full exclusion through a (d)(4) formulary. *See* 42 U.S.C. § 1396r-8(d)(4)(D) (state plan must "permit [] coverage of a drug excluded from the formulary . . . pursuant to a prior authorization program"). The Eleventh Circuit also relied on a finding that "approval of the prescribing doctor's first-choice drug is guaranteed in 100 percent of all cases, provided only that he or she make the telephone call." *Meadows*, 2002 WL 31000006, at *1. No such guarantee protects Medicaid beneficiaries threatened by Maine Rx. To the contrary, as the First Circuit noted, Maine "concedes that it will not authorize payment for the first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant." *Pharmaceutical Research & Mfrs. of America v. Concannon*, 249 F.3d 66, 77 (1st Cir. 2001).

reading of subsection (d)(1)(A). *United States v. Fausto*, 484 U.S. 439, 453 (1988) (the "classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute").

The error in the First Circuit's analysis is revealed by its Opinion. The First Circuit failed to consider the overall legislative structure and history and, in particular, failed to consider how its broad (indeed, essentially unlimited) view of the prior authorization provision in subsection (d)(1)(A) could be reconciled with the other provisions (particularly the (d)(4) formulary provision) of the statute with which it was intended to work in concert. *See PhRMA v. Concannon*, 249 F.3d at 76-78. This consideration of one provision in isolation was error. *See, e.g., John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank*, 510 U.S. 86, 94-95 (1993) (in interpreting a complex statute, Court must look at "the language of the governing statute, guided not by a single sentence or member of a sentence, but look[ing] to the provisions of the whole law, and to its object and policy" (internal quotations and citations omitted)); *Brown v. Duchesne*, 60 U.S. (19 How.) 183, 194 (1856) ("And it is well settled that, in interpreting a statute, the court will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute . . . and the objects and policy of the law. . . ."). Because the construction adopted by the First Circuit would overturn the balance established by Congress between ensuring access to drugs and cost savings, it cannot be accepted by this Court.

III. PRIOR AUTHORIZATION AS IMPLEMENTED IN MAINE RX ALSO IS UNLAWFUL BECAUSE IT IS DIRECTLY ADVERSE TO — RATHER THAN IN THE "BEST INTERESTS OF" — MEDICAID BENEFICIARIES.

There can be no dispute that Maine Rx does not serve — and, in fact, actually disserves — the interests of Medicaid beneficiaries in Maine. The program expressly contemplates restricting access of Medicaid beneficiaries to necessary prescription drugs (through prior authorization) in order to secure rebates for a non-Medicaid (and not universally needy) population. Even if prior authorization were otherwise freely available under the Act, which the foregoing analysis shows that it is not, this anti-beneficiary purpose is contrary to the Act and must not be sustained.

Congress requires states to provide covered Medicaid services in a manner consistent with "the *best interests* of [Medicaid] *recipients*." 42 U.S.C. § 1396a(a)(19) (emphasis added). The Social Security Act requires a focus on *recipients*' best interests, not those of the states' population as a whole. Individual Medicaid recipients are not well-served by restricting their access to prescription drugs. Whatever authority states have to "subject to prior authorization any outpatient drug," 42 U.S.C. § 1396r-8(d)(1)(A), this grant cannot be read untethered from the moorings of the remaining provisions of Section 1396r-8. *United States v. Sun-Diamond Growers of Calif.*, 526 U.S. 398, 406 (1999) (holding that "the more natural meaning, especially given the complex structure of the provision," of a phrase including the term "any" was that "any" referred to "for or because of some particular" rather than "all").

The First Circuit recognized that Maine Rx uses Medicaid tools outside the strictures of a federally approved Medicaid State plan, but held that Maine Rx was nonetheless an acceptable use of the Medicaid program. The First Circuit's conclusory assertion that the absence of a Medicaid purpose "does not mean that the prior authorization scheme *conflicts* with the objectives of the Medicaid program" cannot be countenanced. *PhRMA v. Concannon*, 249 F.3d at 76. Indeed, that conclusion flies in the face of the fact that Maine Rx will restrict beneficiary access to prescription drugs, contrary to Congress' commitment to beneficiaries in 42 U.S.C. § 1396a(a)(19) and in the OBRAs. "[T]his theory . . . is implausible even in the abstract, but even more so in light of the historical principles" of the statute in question. *United Savings Ass'n of Texas v. Timbers*, 484 U.S. at 373. Likewise, the First Circuit's conclusion that prior authorization can be used for any purpose whatsoever[13] simply cannot be squared with the best interests provision of the Act and the carefully structured limitations of (d)(2) and (d)(3). *See* 42 U.S.C. §§ 1396a(a)(19), 1396r-8(d)(2), (d)(3).

13. *PhRMA v. Concannon*, 249 F.3d at 76 ("we are not convinced that the Medicaid statute is concerned with the motivation behind imposing prior authorization, so long as the [24/72] requirements are satisfied").

CONCLUSION

The Medicaid statute contemplates that states will use prior authorization to restrict patients' access to certain prescription drugs only in very specific circumstances — in combination with a carefully crafted formulary, or to control fraud and abuse, but always in keeping with the overarching goal of providing for the best interests of Medicaid recipients. *Any* use of prior authorization unhooked from Medicaid's purposes for such an added administrative burden *necessarily* conflicts with the objectives of Medicaid.

As the Solicitor General recognized, "Congress assuredly did not intend that a State would use a requirement of prior authorization for the prescription of drugs for Medicaid beneficiaries in a manner that would burden the ability of Medicaid recipients to receive covered drugs without serving *some* purpose related to Medicaid." U.S. Br. at 14 (emphasis added). Further, the Solicitor General explicitly recognized that "no Medicaid purpose appears to be served" by the Maine Rx program. U.S. Br. at 16. In these circumstances, the program cannot be sustained and the decision below must be reversed.

Respectfully submitted,

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Pharmaceutical Research & Manufacturers of America,

Petitioner,

v.

Kevin Concannon, Commissioner, Maine Department of Human Services, and G. Steven Rowe, Attorney General of Maine,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

AMICUS CURIAE BRIEF OF LEGAL SERVICES ORGANIZATIONS REPRESENTING MEDICAID BENEFICIARIES IN SUPPORT OF NEITHER PARTY

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INTERESTS OF *AMICI CURIAE*

Amici represent low-income Medicaid beneficiaries in two states in which the type of drug formulary scheme with prior authorization/supplemental rebates at issue in this case has been implemented (Florida) or is about to be implemented (Connecticut).[1] These beneficiaries have a direct interest in this litigation because prior authorization, a necessary component of the scheme at issue, can result, and has resulted in other states, in significant restrictions in access to prescription drugs for needy Medicaid beneficiaries. Although PhRMA has purported to represent the interests of Medicaid clients in this litigation, it is clearly motivated not by such concerns but by the profit interests of its members, and therefore it cannot adequately present the concerns of low-income Medicaid clients in the various states where the challenged scheme has been or is soon to be implemented. In addition, given the arguments being made by PhRMA, any decision on the legality of the Maine scheme will likely include an assessment of the impact of that scheme on Medicaid beneficiaries, such that the Court will benefit from hearing their perspective.

PRELIMINARY STATEMENT

This brief does not address the legality or illegality under the Medicaid Act or Commerce Clause of the Maine Rx scheme consisting of supplemental rebates and prior authorization imposed on Medicaid recipients with respect to those drugs manufactured by companies which refuse to pay them. Pharmaceutical manufacturers engage in a variety of practices designed to artificially inflate the prices of prescription drugs. States understandably seek to combat this trend, since a significant and growing proportion of their expenditures under their respective Medicaid programs are for prescription drugs. However, the particular state practice of prior authorization ("PA") has the direct consequence of restricting access to prescription drugs for Medicaid recipients, and the specific scheme at issue intentionally restricts access in order to induce drug manufacturers to pay supplemental rebates precisely to avoid these restrictions.

As the Court has noted, in creating the Medicaid program, Congress recognized that "'these people are the most needy in the country and it is appropriate for medical care costs to be met, first, for these people.' " Schweicker v. Hogan, 457 U.S. 569, 590 (1982), quoting H.R. Rep. No. 213, 89th Cong., 1st Sess., 66 (1965). It is therefore important for the Court to recognize the potential harm to Medicaid clients when PA is imposed without due consideration of the interests, needs and special problems of Medicaid beneficiaries, as well as the protections for such beneficiaries intended by Congress.

To assist the Court, *amici* summarize the basic legal protections for Medicaid clients set forth in the Medicaid Act and describe some of the problems with PA for patients generally. They then discuss the particular problems for Medicaid clients created by PA, particularly as it has been imposed in some other states.

RELEVANT MEDICAID PROVISIONS

Congress adopted the Medicaid program in order to

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[1] Consent to the filing of this brief has been obtained from both parties to this litigation. No party or counsel for a party in this litigation has contributed to the writing of any part of this brief. No monetary contribution toward this brief has been provided by any entity other than *amici curiae*.

"furnish ... medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services...." 42 U.S.C. § 1396. With that overarching purpose, Congress has imposed strict and detailed requirements on state Medicaid plans in order to protect Medicaid beneficiaries, as set forth in 42 U.S.C. § 1396a. One of these requirements is that each state's Medicaid plan "provide such safeguards as may be necessary to assure that ... care and services will be provided, in a manner consistent with simplicity of administration and the best interests of recipients." 42 U.S.C. § 1396a(a)(19).

Another important requirement applicable to all categories of services under Medicaid is that assistance under the Medicaid program "be furnished with *reasonable promptness* to all eligible individuals." 42 U.S.C. § 1396a(a)(8)(emphasis added). And related to this requirement is the mandate that the state plan "provide for granting an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness." 42 U.S.C. § 1396a(a)(3). "Reasonable promptness" has long been held to apply to requests for individual services under Medicaid, as well as eligibility for Medicaid at large. See Ladd v. Thomas, 962 F. Supp. 284, 290-91 (D. Conn. 1997); Kessler v. Blum, 591 F. Supp. 1093 (S.D.N.Y. 1984). See also 42 C.F.R. §§ 435.906 and 435.930(a). Thus, in order to comply with these provisions, the administrative procedures of a state, including those with respect to any prior authorization system, must assure prompt access to all covered treatments under a given state's Medicaid program, and, if services are denied, must do so only pursuant to an individualized determination of medical necessity, and in compliance with due process requirements. See Weaver v. Reagan, 886 F.2d

194, 199-200 (8th Cir. 1989); Visser v Taylor, 756 F. Supp. 501, 507 (D. Kan. 1990); Jeneski v. Myers, 209 Cal. Rptr. 178, 189 (Cal. Ct. of App. 1985).

Congress also provided that any system of prior authorization for prescription drugs under a fee-for-service Medicaid program must have specific protections, including a 24-hour turnaround time on all requests for prior authorization, and an automatic three-day supply in emergency situations. 42 U.S.C. § 1396r-8(d)(5). However, as discussed below, these pharmacy-specific protections do not protect the thousands of Medicaid beneficiaries whose requests for non-formulary drugs are denied or who, because of confusion and ignorance of PA requirements, are unable to even initiate the PA process.

INHERENT PROBLEMS WITH PRIOR AUTHORIZATION

Prior authorization for prescription drugs is inherently problematic for patients for several reasons, most of which relate not to the prior authorization process itself, but to the failure of the process to even be initiated, owing to ignorance of the system and its details, among both patients and their doctors. Each of these problems for patients generally, whether or not they are covered under a Medicaid program, is discussed below.

First, Medicaid is not the only health insurance program that applies PA to prescription drugs. Each plan that imposes PA has sharply varying rules as to when it is imposed and how one requests PA. United States General Accounting Office, *PRESCRIPTION DRUG BENEFITS: Impact of Medicare HMOs' Use of Formularies on Beneficiaries*, GAO/T-HEHS-99-171, at 4 (July 20, 1999)(Statement of William J. Stanton before the Special Committee on Aging,

U.S. Senate) (available on line at www.gao.gov). Physicians typically must deal with many health plans to run a practice. Many health plans have their own unique formulary, which is premised in part upon whatever current agreements the plan has made with specific drug manufacturers -- whichever drug is the least expensive in a given classification for that particular plan will tend to be on the formulary; the others in the classification will generally not be on the formulary. Id. at 3-4. Moreover, health plans change their formularies with some frequency (generally, at least quarterly), based on the introduction of new drugs and, more importantly, renegotiation by each plan with the drug companies, based on the availability of new generic products and other issues. The number and sheer length of these drug formularies create enormous difficulty for physicians to keep track of which drugs are on which formularies in any given month or quarter. As a result, it is not uncommon for physicians to prescribe drugs which are not on the formulary of the insurance plan for a particular patient (assuming that the doctor even knows what plan is paying for the prescribed medication at the time it is prescribed) without first requesting the necessary PA.

Second, because patients in any health plan routinely obtain access to prescription drugs by presenting a prescription at the pharmacy, expectations are created that this is the manner in which one should proceed to obtain drugs prescribed by a physician. In fact, this procedure generally works for patients. However, in those cases in which PA is required because the drug is not on the formulary, but such authorization has not previously been obtained, the patient presents the prescription and it is not filled.

Third, when the prescription is denied at the pharmacy due to the lack of PA, this information is often not accurately communicated to patients such that they even know about the

availability of PA, let alone the procedure to obtain it. The way that patients might learn of such authorization requirements is through the pharmacist, who types in the request for PA on his or her computer terminal. This computer is linked to the specific health insurer or HMO's pharmacy benefit management computer system. A "yes" or "no" to payment is automatically provided without any human intervention, based on the computer program run by the pharmacy benefit management company, and the pharmacist can convey to the patient the result so obtained. See Hernandez v. Medows, Case No. 02-20964, 2002 WL 31060425, at *5 (S.D.Fla. Aug. 26, 2002)(Ruling Granting Class Certification). However, often the automatic computerized response indicates a rejection for lack of coverage, without indicating that the drug may, in fact, be obtained through PA. Particularly in this situation, the pharmacist is likely to suggest either out-of-pocket payment for the drug or that the patient contact his or her doctor to obtain a prescription for a different drug. The result is that the patient generally is presented with the choice of either direct payment or receiving no drug at all.

Fourth, because some commercial plans use a "closed" formulary, under which non-listed drugs are simply unavailable, the physician may not know that non-listed drugs are available for Medicaid patients through PA. Even if he or she is aware that a non-formulary drug is available through PA through a particular plan, the physician will often change to a different drug which is on the formulary in order to avoid going through a burdensome PA process, see *Report on Prescription Access Hotline (April 22- June 14, 2002). Final Statistical Report* (Mental Health Association in Michigan and Michigan Association for Children with Emotional Disorders), June 24, 2002, at 1-3 ("Michigan Final Statistical

Report")(Lodging with the Court), see also David Mechanic, *Are Patients' Office Visits with Physicians Getting Shorter?*, 334 New Eng. J. Med., Jan. 18, 2001, at 198-204 (the mean duration of a doctor's office visit in 1998 was 18.3 minutes per patient). In fact, this is a primary goal of the HMOs in using formularies. While in many cases such self-censoring by physicians does not cause patient harm, it can create health problems where the alternative formulary drug is not as effective as the drug that the physician would have prescribed if it were readily available without PA, or it causes side effects or adverse drug interactions not present with the originally prescribed non-formulary medication. Id. at 2.

PARTICULAR PROBLEMS CREATED FOR MEDICAID BENEFICIARIES BY THE IMPOSITION OF PRIOR AUTHORIZATION

The above description of the problems with PA apply to patients generally. However, in the case of the typical middle income enrollee in a commercial HMO, there are several options available to obtain a prescription drug, when the enrollee's plan rejects the pharmacy's claim for payment: (1) he or she can pay up-front to obtain the PA-only drug and try to get reimbursed later; (2) he or she will generally have a sufficient educational level and skills to follow through with the doctor or the insurance company, to obtain authorization for the drug the doctor originally prescribed; (3) after approval is obtained, he or she will have transportation to readily return to the pharmacy to obtain the prescription.

It has been suggested in the course of this litigation that PA is not that burdensome for Medicaid patients, as it is often applied in the commercial employer-based health insurance context. However, the circumstances are significantly different for Medicaid recipients. Collectively, these circumstances

mean that PA creates qualitatively different obstacles to access than for middle-income employer-based insurance participants. Peter J. Cunningham, *Affording Prescription Drugs: Not Just a Problem for the Elderly* (Center for Studying Health System Change), Research Report No. 5, at 4, 7 (April 2002)(hereinafter, "Cunningham")(available on line at www.hschange.org). It is therefore imperative that states proceed with great caution when implementing PA schemes for Medicaid recipients.

First, individuals qualify for Medicaid only if they fall into one of the specific categories of low-income individuals covered by this program. The primary categories under which poor people can qualify for Medicaid are being elderly, blind or permanently and totally disabled, being a pregnant woman, or being a member of a family with minor children. 42 U.S.C. § 1396a(a)(10)(A)(i) and (ii). However, the most basic requirement is that the individual have both a very low-income and very few assets. As this Court has noted, "[i]n structuring the Medicaid program, Congress chose to direct those limited funds to persons who were most impoverished and who – because of their physical characteristics – were often least able to overcome the effects of poverty." Schweicker v. Hogan, 457 U.S. at 590. Over half of adult non-elderly Medicaid recipients, including individuals who qualify because they are in families with minor children, have incomes below the federal poverty level. Cunningham, at 4. For those receiving Medicaid because they are elderly, blind or disabled, in 45 states their income must be at or below 74 per cent of the federal poverty level. The Henry J. Kaiser Family Foundation, *State Health Facts Online*, 50 State Comparisons, Medicaid and CHIP, Medicaid Eligibility Levels for Other Enrolled Groups (available online at http://www.statehealthfacts.kff.org.). Thus, in almost all cases, Medicaid beneficiaries lack the resources to pay up-front at the drug store to obtain a

prescribed drug rejected for lack of PA. See Dodson v. Parham, 427 F. Supp. 97, 108 (N.D. Ga. 1977); Stephen B. Soumerai, et al., *Effects of Limiting Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia*, New Eng. J. Med., Sept. 8, 1994; 331: 650-655, at 650 (hereinafter, "*Effects of Limiting Medicaid Drug-Reimbursement*"). This means that the Medicaid patient who is denied access at the pharmacy counter to a prescribed medication will walk out, not only without the originally prescribed drug, but with **no drug at all**, in the vast majority of cases.

Second, Medicaid clients are sicker than the general population, with a significantly higher incidence of chronic disease. See Schweicker, 457 U.S. at 590; Vargas v. Trainor, 508 F.2d 485, 489 (7th Cir. 1974); Cunningham at 4. More than one-fourth of adult non-elderly Medicaid beneficiaries have multiple chronic conditions, compared to less than 10% of such individuals with employer-based coverage. Cunningham at 4. Further, it is projected that, between now and 2010, the increase in the Medicaid enrollment rate for the blind and disabled will be twice that for all other enrollees. United States Department of Health and Human Services, *"A Profile of Medicaid, Chartbook 2000"*, p. 18, Figure 1.5 (available online at http://cms.hhs.gov/charts/medicaid/2Tchartbk.pdf.). Since Medicaid patients have a statistically lower level of health, given their poverty and disproportionate representation of individuals with chronic disease. Cunningham, at 4, 7, their health can quickly decline, with the physician who prescribed a drug to arrest such decline not even knowing that his or her prescribed treatment is not being applied. Indeed, previous restrictions on Medicaid beneficiaries' access to prescription drugs imposed in the past by other states have resulted in increased emergency mental

health services and increased institutionalization (often irreversible), both increases incurred at state expense. Soumerai, *Effects of Limiting Medicaid Drug-Reimbursement*; Stephen B. Soumerai, et al., *Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*, New Eng. J. Med., 1991; 325:1072-1077.

Third, literacy skills are disproportionately lower for Medicaid recipients than for the population at large. See New York City Unemployed and Welfare Council v. Brezenoff, 742 F.2d 718, 722 (2d Cir. 1984). As such, information about the details of PA and how to obtain it is less likely to be effectively communicated to such recipients by a pharmacist who has received a computerized message that a drug cannot be filled and correctly identifies the cause as lack of PA.

Fourth, even if they speak English, receive accurate information from the pharmacist about the PA process, and make obtaining the prescribed drug a priority, Medicaid recipients are much more likely to lack the resources to take affirmative steps to negotiate a complicated PA process after a rejection at the pharmacy occurs, assuming that they are advised of this option by the pharmacist. See Goldberg v. Kelly, 397 U.S. 254, 264 (1970); Vargas, 508 F.2d at 489-90; Ortiz v. Eichler, 616 F. Supp. 1046, 1062 (D. Del. 1985), aff'd 794 F.2d 889 (3d Cir. 1986). Even such basic tasks as making a long-distance phone call to the pharmacy benefit management company are difficult, since many Medicaid recipients lack the resources to make long-distance calls and a substantial number do not even have telephones. If they are employed, they often work in service jobs which will not allow them to take time off during the day to make these necessary calls and receive return calls.

Fifth, more Medicaid recipients lack private

transportation, and are physically disabled, than the general population. They thus encounter significant difficulties in simply returning to the pharmacy to obtain a PA-only drug, even if they are able to negotiate the PA process and PA is finally obtained. The initial trip to the pharmacy may be one that had to be specially arranged; it may be days before they can arrange another to pick up the prescription which is finally authorized.

These special obstacles for Medicaid clients have largely been ignored by states which have implemented PA. The way that the states have so far implemented PA, tied to formularies in particular, has not worked well for Medicaid recipients.

In Florida and Michigan, two states that have implemented PA in order to obtain supplemental rebates, the short history of such implementation has seen a disturbingly wide-spread level of interference with access to basic medical care. For example, low-income Medicaid patients in Florida are routinely turned away at the drug store without access to needed prescriptions, because the prescribed drug was not on the formulary and required PA, and yet the physician, not having known that the drug required PA, simply wrote a prescription for it without seeking PA. According to documents provided by the State of Florida in pending class action litigation filed by Medicaid beneficiaries, with respect to Florida's procedures for PA, as well as its "four brand limit" imposed on these beneficiaries:

> Defendant's own statistics demonstrate that over *35,000 [Medicaid] recipients in a single recent month were denied coverage* of their prescription drugs or the opportunity for a hearing, including *21, 974 recipients who received no drug at all in the same therapeutic*

> *class*. These numbers exclude those recipients who were denied their prescription claims due to the generic substitution payment policy and those who eventually did receive their doctor's prescription after an unknown period of delay.

Hernandez, 2002 WL 31060425, at *3.

In Michigan, doctors who request PA for their Medicaid patients are routinely denied authorization. In response to this experience, patients are often switched by their Medicaid doctors from non-formulary to formulary drugs, even though the second drug is far less effective than the first for that particular individual.[2] Michigan Final Statistical Report at 2. Michigan Medicaid recipients are routinely denied approval for drugs on which they have been stabilized for months or even years, causing deterioration in their health status. For recipients treated with complex medication regimens, denial of even one drug and substitution with another can have immediate adverse consequences because of negative interactions between medications.

In Florida, a federal district court has recently recognized due process concerns in the implementation of PA, as it is required under 42 U.S.C. § 1396a(a)(3) and 42 C.F.R.§ 431.200, et seq., see Goldberg, 397 U.S. at 267-68. As explained in the recent class certification decision in Hernandez:

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2 Medicaid recipients are entitled to all medically necessary medications, with the exception of a few narrow categories of excluded drugs set forth in federal law. 42 U.S.C. § 1396r-8(d)(4)(D). A client may only be limited to a formulary medication if it is equally effective in treating that particular member's medical condition. See Jeneski, 209 Cal. Rptr. at 189; Visser, 756 F. Supp. at 507.

> With a minor exception, the failure to provide such notice and hearing is uniformly being applied against all members of the Plaintiff class [Florida Medicaid beneficiaries].... Typically, this happens when recipients receive prescriptions from their physicians and then go to a pharmacy to get the prescription filled, and are rejected by a state actor for any number of reasons under Florida's complicated Medicaid law. Such claims are decided immediately by the state actor and the pharmacist receives an electronic message stating whether the drug is covered and therefore whether the claim will be paid, suspended, or denied.... *When coverage is denied for whatever reason, there are no provisions for recipients to receive a written notice in either the Florida Statutes or in the current or proposed administrative rule on the prescription drug coverage.*

Hernandez, 2002 WL 31060425, at *5 (emphasis added).

CONCLUSION

The members of PhRMA have largely brought upon themselves the push by the states to impose prior authorization on their products, as the companies' practices are sharply driving up the states' costs under their respective Medicaid programs. While the states are rightly taking action to address this growing problem, the Court must not lose sight of the fact that the protections for Medicaid beneficiaries provided in the Medicaid Act are designed to protect the health of the most vulnerable members of our society-- not the profits of drug companies.

In its decision below, the First Circuit ruled for Maine,

but cautioned that its decision "was without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the prior authorization requirements 'as applied.' " PhRMA v. Concannon, 249 F.3d 66, 78 (1st Cir. 2001). Since that time, several states have in fact implemented supplemental rebate/PA schemes, solely for the purpose of saving money. *Amici* believe it is important for the Court to be aware that, where supplemental rebates have been linked with prior authorization requirements, significant harm has befallen Medicaid recipients. They have been denied reasonably prompt access to prescription drugs because of difficulties inherent in the administration of a Medicaid formulary program which exists in the midst of dozens of similar programs, each with its own unique requirements for authorization of excluded drugs. *Amici* therefore exhort the Court to recognize the special obstacles to health care access facing Medicaid recipients under supplemental rebate/PA schemes and the caution with which states must proceed if they seek to implement such schemes.

Dated: September 20, 2002

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IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH and MANUFACTURERS OF AMERICA,
Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENTOF HUMAN SERVICES, and THE MAINE ATTORNEY GENERAL,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF *AMICI CURIAE* MAINE COUNCIL OF SENIOR CITIZENS, VIOLA QUIRION, MICHELLE CAMPBELL AND RICHARD DONAHUE, M.D. IN SUPPORT OF KEVIN CONCANNON AND G. STEVEN ROWE AND AFFIRMANCE

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QUESTIONS PRESENTED

Amici will address both questions presented in the petition:

1. Whether the purpose of the federal Medicaid statute, 42 U.S.C. §1396 *et seq.*, is frustrated if Maine considers *any* drug for prior authorization status as a result of the drug manufacturer's choice not to negotiate with the State better prices for uninsured and underinsured consumers not eligible for Medicaid?

2. Whether Maine violates the Commerce Clause by negotiating with out-of-state manufacturers for discounts for uninsured or underinsured consumers?

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INTERESTS OF *AMICI CURIAE*

Amici Curiae are two individuals, and an association and a doctor representing individuals, who lack health insurance coverage for the cost of their prescription drugs and who intend to take advantage of benefits offered under the "Maine Rx Program" established by the statute at issue in this case. They have been granted "amicus plus" status by the United States District Court for the District of Maine in the proceedings below, in response to a motion to intervene filed subsequent to the Court's granting of a preliminary injunction. In the appeal of the District Court's decision to the First Circuit Court of Appeals, they filed an *Amici Curiae* brief. The parties have consented to this filing of an *Amici Curiae* brief.[1] *Amici* also have submitted a lodging.

Viola Quirion, who retired after 44 years of working at a shirt factory, has no health insurance coverage. She requires the drug Relafen for her arthritis and Prilosec for a hiatal hernia. Without Relafen, Ms. Quirion will rapidly lose her ability to walk and would have to go into a nursing home. She has either cut her pills or skipped pills to reduce her drug costs. She also has skipped meals and eaten the cheapest meals she can find in order to save money for medicine, but those tactics cause her other health problems. Aff. of Viola Quirion. (Addendum to First Circuit Court of Appeals *Amici Curiae* Brief at 1) (hereafter Add. of First Cir. Amici Brief).

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[1] No counsel for a party authored this brief *Amici Curiae* in whole or in part. The Alliance for Retired Americans (with which *Amicus* Maine Council of Senior Citizens is affiliated) and the American Federation of Labor and Congress of Industrial Organizations contributed to the costs of printing this brief. The American Association of Retired Persons may contribute to the cost of legal research but has not directed such research. Aside from these, no other person or entity beyond Amici and their counsel has made a monetary contribution to the preparation or submission of this brief.

Michelle Campbell is a young mother of four living in the island community of North Haven, Maine, with her children and husband. Ms. Campbell's family has no health insurance and does not qualify for Medicaid. Because her husband is a fisherman, her family's income varies by the season. Her family's income is lowest during the winter, when her children are most susceptible to illness. Her 10-year-old daughter suffers from reactive airway disease and needs inhalers that cost about $75 per month. In the winter, her daughter must take Singular, which costs another $100 per month. Aff. of Michelle Campbell (Add. of First Cir. Amici Brief at 3).

The Maine Council of Senior Citizens is a membership organization that advocates for the interests of Maine seniors. Many of the Council's members are forced to make life-threatening choices between medicine and food or heating oil. Many skip dosages, share prescriptions or don't fill their prescriptions at all. Aff. of John Moran (Add. of First Cir. Amici Brief at 5).

Richard J. Donahue, M.D., is a family practice physician at the Islands Community Medical Center in Vinalhaven, Maine. Through his practice, he is aware of patients who have refused or misused medications because of the high cost of prescription drugs. Generally, his cardiac patients and patients suffering from hypertension are more apt to base decisions regarding their medications on cost, because symptoms of those conditions are often subtle, and it is difficult for patients to justify buying drugs over other essentials when they are feeling well. Dr. Donahue believes that making drugs more affordable through the Maine Rx Program will substantially improve his patients' health. Aff. of Richard J. Donahue, M.D. (Add. of First Cir. *Amici* Brief at 7).

STATEMENT OF THE CASE

The compelling stories of *Amicus Curiae* typify those of thousands more uninsured Maine citizens who lack insurance for prescription drugs and therefore must pay out-of-pocket for their medications at some of the highest prices in the world. Widespread reports of uninsured senior citizens and other chronically ill residents not taking their prescriptions, skipping doses, or sacrificing food or heat in order to purchase medicines prompted the Maine Legislature to address the growing public health crisis in 2000 by enacting the Maine Rx Program by an overwhelming bipartisan consensus. 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599).

The Maine Rx law authorizes the State of Maine to operate as a pharmaceutical benefits manager (PBM) with the authority to negotiate prescription drug rebates to the State in order to reduce the out-of-pocket cost of drugs for Maine's uninsured population. Under the Maine Rx Program, the State links market share and volume to rebates from manufacturers, a market incentive common to private-sector PBMs and familiar to pharmaceutical manufacturers. While enrollment in the Program is open to all Maine residents, only those residents without alternative prescription drug benefits through health insurance or through some government program will benefit by enrolling.

As the First Circuit Court of Appeals recognized, the Maine Rx law "is predicated on the economic reality that volume buying of prescription drugs by Medicaid administrators, insurance companies and health maintenance organizations ('HMOs') resulted in substantially lower prices for these entities than for individual purchasers," such that individual elderly purchasers were paying 86 percent higher prices than those charged the federal government and HMOs. *Pharmaceutical Research and Mfrs. Of Am. v. Concannon*, 249 F.3d 66, 71 (1st Cir. 2001) (hereafter *PhRMA*).

Participation by drug manufacturers in the Maine Rx Program is voluntary. The statute does not attempt to regulate drug manufacturers' prices; it authorizes the State to use its market share to negotiate rebates. The Maine Commissioner of Human Services is expressly instructed by the statute to use his "*best efforts* to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program." 22 M.R.S.A. §2681(4)(B) (emphasis added). The Legislature clearly envisioned that some manufacturers will not participate. The law strengthens the bargaining position of the Commissioner by making public the names of manufacturers who elect not to enter into rebates and proposing those manufacturers' products for "prior authorization" under the State's Medicaid program, "as permitted by law." *Id.* at §2681(7). In so doing, the statute adopts a market model rather than a regulatory one; recalcitrant manufacturers face no civil or criminal penalties.

The Act creates an incentive for drug manufacturers to participate in negotiations by threatening to shift shares of Maine's Medicaid prescription drug market to competitive drugs of participating manufacturers. Drug manufacturers also anticipate that any shift in the Medicaid market will be exaggerated by a tendency among health care professionals to prescribe the same drugs to their non-Medicaid patients as they are accustomed to prescribing to their Medicaid patients.

Prior authorization is not the goal of the Maine Rx Program. If the State successfully negotiates drug rebates with manufacturers, there will be no increased use of prior authorization due to the Maine Rx Program.

Before the Maine Rx program could go into effect, the Petitioner trade group brought this facial challenge to the law and obtained a preliminary injunction in the United States District Court for the District of Maine. On appeal, the First Circuit Court of Appeals found no constitutional violation by the Maine Rx law, but stayed its mandate to permit this

appeal of a facial challenge at the preliminary injunction stage of litigation.

Although the State timely and responsibly addressed a public health crisis within its borders by enacting the Maine Rx Program, it has never had the opportunity to put the Program to the test. It has been denied the opportunity to determine what success might result from a market-model negotiation process; to demonstrate that Maine Rx will not impose a burden on Medicaid beneficiaries; and to provide the first ounce of relief to its growing population of uninsured needy, ill, and elderly people. Ironically, the Petitioner—a trade group for the industry whose pricing practices created this public health crisis by forcing Maine's uninsured to pay the highest prices—now claims to act on behalf of Maine's needy.

SUMMARY OF ARGUMENT

In this facial challenge, the Petitioner trade group cannot establish that any application of the Maine Rx Program necessarily will frustrate the congressional purpose of the joint state and federal Medicaid program in violation of the Supremacy Clause. States are expressly permitted by federal statute to require prior authorization for any prescription drug, and some states historically elected to require prior authorization for every drug. Congress was not concerned with the states' motivation for prior authorization. Furthermore, the purpose of the Maine Rx law is consistent with the purpose of the Medicaid program, and even advances that purpose, by making prescription drugs more accessible to persons lacking insurance coverage.

The Maine Rx law does not regulate the terms of out-of-state transactions or otherwise violate the dormant Commerce Clause. Rather it authorizes Maine to become a market participant by taking on the role of a pharmaceutical benefits manager (PBM) for Program enrollees, negotiating drug prices for that group in the same manner as PBMs in the

private market. Manufacturer rebates under the Maine Rx Program depend on voluntary negotiations with individual drug companies. While rebates may affect the profits of individual drug companies, that impact will not be a result of regulation but of negotiation and competition for market share.

The Petitioner's complaint does not challenge the Maine Rx Program on the basis that it requires approval by the federal government as an amendment to Maine's Medicaid plan, and that issue is not properly before this Court for review. Similarly, the Petitioner did not argue discrimination against interstate commerce in the proceedings below, and therefore waived its right to do so at this late date.

ARGUMENT

I. MAINE'S RX PROGRAM IS NOT PREEMPTED BY FEDERAL LAW.

A. The Petitioner Cannot Establish That Any Application of the Maine Rx Program Will Frustrate the Purposes of Medicaid.

The hurdle that the Maine Rx law must clear in order to pass constitutional muster under the Supremacy Clause is not a high one. The only basis asserted by the Petitioner for preemption in this case is implied conflict preemption. To prevail, the Petitioner must show that compliance with both the Maine Rx law and the federal Medicaid law is impossible, or that the Maine Rx law interposes an obstacle to the achievement of Congress' discernible objectives. *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992).

Moreover, the Petitioner's challenge to the Maine Rx Program on Supremacy Clause grounds is a facial challenge, in which "the challenger must establish that no set of circumstances exists under which the Act could be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987); *see also Anderson v. Edwards*, 514 U.S. 143, 155 n.6 (1995) (citing

Salerno); *Reno v. Flores*, 507 U.S. 292, 301 (1993) (same); *Rust v. Sullivan*, 500 U.S. 173, 183 (1991) (same).

In essence, the Petitioner contends that Maine may not enlist its expressly granted authority of prior authorization within its Medicaid program to improve access to necessary health care for persons outside the Medicaid population. Consequently, the Petitioner must show that the placement of *any* drug onto the Medicaid prior authorization list, when consideration for placement was triggered by the Maine Rx Program, will frustrate the objectives of Congress to provide medical services to those persons whose "income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. §1396. It is not enough that the Petitioner establish that the *potential* exists for a State to operate the Maine Rx Program in a manner that would interfere with Congress' objectives.

Petitioner's attempt to prevent the State from implementing the Maine Rx law in order to address "one of the serious [public health] problems of our time," *PhRMA*, 249 F.3d at 80, should not be treated lightly. Protecting the health and safety of the public is traditionally a legitimate role of, and within the authority of, the State. *Hill v. Colorado*, 530 U.S. 703, 715 (2000); *Metropolitan Ins. Co. v. Mass.*, 471 U.S. 724, 758 (1985). "[T]he historic police powers of the States [are] not to be superceded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." *New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Insurance Co.*, 514 U.S. 645, 655 (1995) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

The Petitioner has failed to meet its burden. Nothing on the face of the Maine Rx statute makes it impossible to implement both that law and Medicaid or frustrates the objectives of Congress under the Medicaid program.

B. Maine Rx Serves a Purpose Consistent With Medicaid.

The State acted within its broad scope of discretion when it enacted the Maine Rx Program and, if implemented, the Program will benefit Medicaid. Indeed, the purposes of the two laws are entirely consistent. The purpose of the Medicaid program is to enable states to provide medical services to those persons whose "income and resources are insufficient to meet the costs of necessary medical services," 42 U.S.C. §1396, whereas the purpose of the Maine Rx Program is to provide "greater access to prescription drugs" by making them more affordable to uninsured or underinsured persons. 22 M.R.S.A. §2681(1). The inability of the uninsured to pay for their prescription drugs was the clear motive for enacting the Maine Rx Program. "They have to take the prescription back, go home and say, 'I just can't have it filled.'" Me. Legis. Rec. S2496 (2nd Reg. Sess. 2000) (Statement of Sen. Pingree).

Maine Rx offers a benefit to a targeted population—those who must pay out of their own pocket for prescription drugs. Although the Maine Rx Act does not impose any means test on enrollees, the de facto beneficiaries of the program are persons who are uninsured, underinsured and not eligible for Medicaid. Any person whose prescription drug costs are substantially paid by an insurer will not realize any savings by enrolling in the Maine Rx Program. Those persons with the most significant unmet need for affordable prescription drugs—primarily the elderly and those with devastating acute or chronic illnesses—are most likely to enroll in the program. This use of natural targeting offers advantages over rigid alternatives such as a means-test. It reduces bureaucratic costs and inefficiencies, renders enrollment easy, minimizes stigma, and increases flexibility for enrollees with varying incomes and health problems.

If a benefit to Medicaid need be discerned, the Maine Rx Program provides one. By making drugs more affordable to persons without Medicaid or private insurance, Maine Rx will decrease, or slow the rate of increase of, the number of Medicaid enrollees, thereby conserving resources for existing Medicaid beneficiaries.

This effect is reported in the literature of the field. When people are unable to purchase necessary medications, skip their medications for cost reasons, or choose medications over other essentials for their health, their physical conditions are likely to worsen, and they are more likely to be driven into poverty, hospitals and nursing homes. *See, e.g.*, Aff. of Viola Quirion ¶ 3 (stating that without the prescription drug Relafen, that she can ill afford, she would lose her "ability to walk in a very short time and would have to go into a nursing home") (Add. of First Cir. Amici Brief at 1); Steven B. Soumerai, Sc.D., *Effects of Medicaid Drug-Payment Limits on Admission to Nursing Homes*, 325 New Engl. J. Med. 1072 (1991) (reporting that increased prescription drug costs to frail, low-income, elderly patients increases their risk of institutionalization in nursing homes and may increase Medicaid costs) (First Cir. Amici App. at 115); Steven B. Soumerai, Sc.D., *Effects of Limiting Medicaid Drug Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia*, 331 New Engl. J. Med. 650 (1994) (reporting that increased costs of prescription drugs to low-income patients with chronic mental illnesses can increase their use of acute mental health services and increase costs to the government) (First Circuit Court of Appeals Amicus App. at 122); Alyce S. Adams, *Use of Antihypertensive Drugs by Medicare Enrollees: Does Type of Drug Coverage Matter*, Health Affairs, Jan.-Feb. 2001 (concluding that government should be quite concerned about underuse of clinically important drugs in patients without insurance coverage or

with self-purchased coverage because of increased likelihood of adverse events).

Understandably, when consumers cannot afford their medications, they don't comply with their doctors' instructions on doses, or they resort to sharing medications or self-prescribing with cheaper substitutions. Aff. of Viola Quirion at ¶ 5 (stating that she is forced to cut pills or skip dosages in order to afford her medications) (Add. of First Cir. Amici Brief at 2); Aff. of John Moran ¶ 6 (noting that members of his group skip dosages, share prescriptions or don't fill their prescriptions) (Add. of First Cir. Amici Brief at 6); *Problems With Prescription Drugs Highest Among Elderly*, American Family Physician, Dec. 1983 (noting non-compliance by elderly with their medications, by not taking the medication, not taking at the proper time or in the proper dose, swapping drugs with friends, and self-prescribing over-the-counter drugs).

The United States agrees that Medicaid is likely to benefit from making prescription drugs more affordable to non-Medicaid consumers. "A prescription drug discount for non-Medicaid populations, made possible by encouraging manufacturers to give rebates, could significantly decrease the chance that such individuals will become Medicaid-eligible as either categorically or medically needy individuals, and thereby drain the State's scarce Medicaid resources." Brief for the United States at 29; *see generally* Brief for the United States at 25-30.[2] The United States' only objections to the Maine Rx law appear to be the absence of a means test and a belief that states must obtain federal approval before implementing programs like Maine Rx.

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[2] Petitioner can hardly disagree. "The value of new and better medicines stems not only from the improved treatment of disease, but also from a reduction in other health care costs, increased productivity and better quality of life." *See* PhRMA web site at *www.phrma.org/issues/valuemedicine*.

The United States sets the bar too high. Under an implied preemption challenge, there is no requirement that the state statute benefit the federal law at issue, let alone be narrowly tailored to benefit that law.

A means test within the Maine Rx Program would not increase the benefit to Medicaid, nor lessen any burden. If there is any burden to Medicaid beneficiaries from the use of prior authorization to obtain market leverage with drug manufacturers (which Amici assert there is not), *precisely the same burden exists* irrespective whether the Maine Rx Program is targeted to a means-tested population or whether the program is of benefit to all uninsured or underinsured Maine residents. Nothing in the record suggests that not including a means test within Maine Rx results in a greater need for prior authorization under Medicaid. There simply is no correlation between the amount of benefit to the uninsured or underinsured non-Medicaid population and the amount of inconvenience, if any, to Medicaid beneficiaries.

Furthermore, when the United States contends that the Maine Rx Program insufficiently targets a needy population for affordable drugs, it takes into consideration only half of the equation—the income side—and not the extent to which drug costs may exceed the ability of many to pay. The growth in prescription drug use and costs is undeniable. A recent study found that persons who spend $5,000 or more per year are the fastest growing group among a population of insured elderly. High- and very high-cost elderly took more than 50 prescriptions per year on average. Cindy Parks, *Growth in Prescription Drug Spending Among Insured Elders: Use of Newer Classes of Medications Moves Elderly Persons Into Higher Cost Groups*, Health Affairs, Sept.-Oct. 2001. Uninsured and underinsured seniors do not have fewer prescription drug needs; they only have a lesser ability to pay.

The fact that Maine has initiated another drug assistance program with a means test (the Healthy Maine Prescription

Program, which program uses Medicaid dollars) does not place the Maine Rx Program in conflict with Medicaid's objectives. Maine would be unwise to rely upon the Healthy Maine Prescription Program alone to address the State's public health crisis, as Petitioner has filed a separate lawsuit challenging the legality of that program as well. That case is pending in the District of Columbia Circuit Court of Appeals. *Pharmaceutical Research and Mfrs. Of Am. v. Thompson*, Docket No. 02-5110. Moreover, the ease of enrollment and other qualities of the Maine Rx Program, in addition to the program's high visibility, are likely to encourage participation among persons who have not enrolled in the Healthy Maine Program. In any case, no one program will achieve 100 percent enrollment of eligible participants. *See, e.g.*, Henry J. Kaiser Family Foundation, *California Seniors and Prescription Drugs*, at 4 (2002) (finding that less than a quarter of California's senior citizens were aware of State's drug discount program enacted two years earlier) (available online at *www.kff.org*). Maine will be more successful extending benefits to the uninsured if they are given alternatives. That is not a novel concept in the world of private insurance, or in the world of other businesses, and should not be so in the arena of public health. In the absence of a necessary obstacle to Congress' objectives for Medicaid, the choice of how to fashion programs to best expand uninsured citizens' access to affordable prescription drugs is properly a policy decision left to the State, through its elected legislature.

C. The Use of Prior Authorization Is Expressly Permitted by Statute.

The use of prior authorization is not a harm to be balanced against the benefit to Medicaid from the Maine Rx Program. It instead is an appropriate tool that Congress expressly provided to the states, and which states have broad authority to manage for their purposes. The issue is not what Congress *intended* regarding the use of prior authorization, but what

authority Congress expressly *gave* the states to use prior authorization. As the First Circuit Court of Appeals concluded, the Medicaid statute does not appear concerned with the motivation behind the states' imposing prior authorization. *PhRMA*, 249 F.3d at 76 (2001).

The Medicaid statute requires states to "provide such *safeguards* as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients . . . ." 42 U.S.C. § 1396(a)(19) (emphasis added). "A State may subject to prior authorization *any* covered outpatient drug" provided that the State implements two safeguards. *Id.* at §1396r-8(d)(1)(A) (emphasis added) (24-hour response time and 72-hour emergency supply).

Provided these safeguards are followed, a State does not act contrary to the best interest of Medicaid beneficiaries as a whole by requiring prior authorization of selected drugs. More to the point, there is no evidence in the record to support the facial challenge that Maine *necessarily* cannot operate its Medicaid program with sufficient safeguards for prior authorization because of the Maine Rx Program.

The plain text of the Maine Rx law incorporates Medicaid's safeguards by requiring that prior authorization be used "as permitted by law." 22 M.R.S.A. §2681(7). In addition, the statute requires the Department of Human Services to administer the Maine Rx Program in a manner that is "advantageous . . . to the enrollees" in Maine's Medicaid program and that will "enhance efficiency" of that program. *Id.* at §2681(13).

The authority of a State to choose any drug or all drugs for prior authorization hardly could be more clear. Nothing in the Medicaid Act prohibits states from using prior authorization to increase efficiencies, reduce (or decrease the rate of growth of) Medicaid expenditures, to favor one brand of

drugs over another, and to favor the use of generic drugs over other drugs.[3] Significantly, when gaining these economies, states are not obligated to devote savings (or avoided costs) to extend Medicaid programs to others, or to expand the scope of Medicaid benefits to the existing Medicaid population.

If Maine has the authority to impose prior authorization for every prescription drug, then it surely has the authority to impose prior authorization on a lesser number of drugs, so long as Maine complies with other conditions of the Medicaid program. Indeed, Maine already imposes, as do other states, prior authorization requirements for numerous drugs.

Maine has never proposed—and the Maine Rx law does not require—a radical amount of prior authorization, under any scenario. Under rules proposed by the State, non-participation by a manufacturer in the Maine Rx Program may trigger a recommendation of that manufacturer's drug for prior authorization to Maine's Medicaid Drug Utilization Review Committee, an advisory board of physicians and pharmacists. The Committee will make the final determination as to prior authorization, consistent with the Medicaid law and "particularly the principle that Medicaid recipients shall be assured access to all medically necessary prescription drugs." Aff. of Kevin Concannon ¶11 (J.A. at 165, 167).

In addition to the Maine Rx law's express provision that prior authorization be used only "as permitted by law," 22 M.R.S.A. §2681(7), Maine's Commissioner of Human Services has said by affidavit in this case that the State will not violate Medicaid requirements in its use of prior authorization. "The Department will not impose a prior authorization requirement in the Medicaid program . . . where the

[3] New Haven Legal Assistance, Florida Legal Services, and National Health Law Program argue as Amici that a burden is placed on Medicaid beneficiaries by any use of prior authorization, which use is clearly permitted by Medicaid. Those Amici would like to read prior authorization out of Medicaid altogether, an issue clearly not before the Court.

imposition of such a requirement would conflict with the requirements of the Medicaid program. Prior authorization requirements will not be implemented so as to prevent Medicaid recipients from obtaining medically necessary prescription drugs." Aff. of Kevin Concannon ¶9 (J. A. at 166-67). Neither will the State subject to prior authorization "any single-source drug that fulfills a unique therapeutic function," regardless of the manufacturer's lack of participation in the Maine Rx Program. Aff. of Timothy S. Clifford, Medical Director for the Maine Bureau of Medical Services, ¶ 8 (J.A. at 147, 148-49).

D. Maine's Use of Prior Authorization Has Not Harmed Beneficiaries.

Actual experience rebuts the contention that prior authorization must harm Medicaid beneficiaries in Maine. Maine now requires prior authorization for 70 drugs in its basic prior authorization program and an additional 65 drugs if dose consolidation protocols are not followed, unconnected with the Maine Rx Program. *See* Letter from Concannon to Preston, Oct. 31, 2002 (Amici Lodging at 1).

Requiring prior authorization for certain drugs has not denied Medicaid beneficiaries necessary medicines. Any Medicaid patient given a prescription for a drug requiring prior authorization is entitled to a 96-hour supply, or a 34-day supply if the prescription is a one-time fill (not eligible for refill), prior to establishing medical necessity through the prior authorization process. *Id.* at 3. In 2001 and the first quarter of 2002, Maine paid for nearly $5.4 million of drugs in accordance with its 96-hour, 34-day policy. *Id.* at 8 (total under heading of "134 Script $").

Critical indicators by which the State might detect problems with prior authorization show that the system is operated without demonstrable harm to Medicaid patients. Although Maine is permitted by the Medicaid law up to 24 hours to respond to a request for prior authorization, the

State's average time to respond to a prior authorization request in 2002 was less than two hours. *Id.* at 2. Since Maine expanded its use of prior authorization in 2001, the number of Medicaid clients being seen by doctors is up (indicating that doctors are just as willing to see Medicaid patients as before prior authorization), the number of adverse events involving Medicaid patients is down, and the number of hospital admissions of Medicaid patients is down. *Id.* at 1-2.

The use of prior authorization by Maine and other states, whether or not in conjunction with reducing drug costs to non-Medicaid populations, is not an extraordinary approach. Rather, it mirrors drug cost management techniques used by private insurers and health maintenance organizations. *Cf.* Ruth B. Timm, Note, *The Intraenterprise Conspiracy Doctrine and the Pharmaceutical Benefit Management Industry: A Proposed Exception to the Copperweld Holding*, 31 Val. U. L. Rev. 309, 311 n.14 (1996) (stating that PBMs in the private market select drugs for a formulary based on the drug's price, effectiveness, safety and side effects, optimally selecting as the "best" drug that which is the most effective and the one most reasonably priced).

The Petitioner itself has reported this trend. A 1999 industry profile released by Petitioner showed that 90 percent of HMOs use formularies in which drugs are approved for payment based on cost, side-effects and therapeutic value. More than a third of HMOs at that time required physicians to adhere to a sequence of treatments, in most cases starting with the lowest-cost therapy. *PhRMA Eyes Delivery, Payment Methods*, Chain Drug Review, April 26, 1999, at Rx22. Drugs that are not on HMO formularies are subjected to prior authorization. For those medications, a prescribing physician must contact the HMO plan representative to request an exception before the HMO will provide coverage. United States General Accounting Office, *Prescription Drug Benefits: Impact of Medicare HMOs' Use of Formularies on Beneficiaries*, GAO-T-HEHS-99-171, July 20, 1999, at 2 (Statement of William J. Stanton before the Special Committee on Aging, U.S. Senate) (available online at *www.gao.gov*).

The State should not be faulted for adopting the prevailing market mechanism for cost containment—prior authorization—in its attempt to make prescription drugs more affordable to its uninsured and underinsured residents. Pooling the State's Medicaid population with its uninsured population to strengthen the State's bargaining position vis-à-vis drug manufacturers makes good economic and fiscal sense.

The United States agrees that using prior authorization under Medicaid to make drugs more affordable to non-Medicaid populations can further the purposes of Medicaid. Brief for the United States at 28-30. Although the United States faults Maine for not obtaining federal approval for a Medicaid plan amendment before implementing the Maine Rx Program, it concedes that that issue is not properly before this Court. Brief for the United States at 29, n.11. The Petitioner did not base its challenge on that ground or argue that issue in the proceedings below. Therefore, the issue need not be addressed by this Court. *See Paterson v. McLean*, 491 U.S. 164, 185 (1989).

II. MAINE'S USE OF ITS MARKET POWER TO NEGOTIATE REBATES FOR MAINE RX ENROLLEES DOES NOT INTERFERE WITH INTERSTATE COMMERCE.

The First Circuit was correct in holding that the Maine Rx Program "represents a novel legislative approach to one of the serious problems of our time" by empowering the State to negotiate rebates for enrollees without regulating transactions between pharmaceutical manufacturers and wholesalers or imposing excessive incidental burdens on interstate commerce. *PhRMA*, 249 F.3d at 80-82 and 84.

Commerce Clause analysis places substance over form, "eschew[ing] formalism for a sensitive case-by-case analysis of *purposes* and *effect*" of the challenged statute. *West Lynn Creamery v. Healy*, 512 U.S. 186, 201 (1994) (emphasis added). The *purpose* of the Maine Rx Program is to reduce the cost of prescription drugs for uninsured citizens by providing the same pharmaceutical benefits management (PBM) services used by private-sector PBMs to reduce costs to other segments of the market. The *effect* is to maximize the State's bargaining power vis-à-vis drug manufacturers desiring access to the Maine Rx and Maine Medicaid markets —markets unserved or underserved by private PBMs. If a manufacturer elects to not negotiate with the State, the State may react by shifting its market share away from that manufacturer's products. The effect is the same regardless of where the manufacturer is located or how it structures its chain of commerce for products destined for the Maine market.

Maine's use of its role as the PBM and payor for Medicaid recipients to leverage better prices for Maine Rx participants does not impede interstate commerce, does not distinguish between interstate and intrastate manufacturers, and does not have the practical effect of controlling prescription drug prices in other states. This simply is not the type of activity that the Commerce Clause was intended to reach. "The dormant Commerce Clause prohibits protectionist state regulation designed to benefit in-state economic interests by burdening out-of-state competitors." *Grant's Dairy-Maine, LLC v. Commissioner of Maine Dep't of Agric., Food & Rural Resources*, 232 F.3d 8, 18 (1st Cir. 2000). There is no protectionism at work here; there is only the State's compelling interest in safeguarding the health and welfare of its own residents. Indeed, because the challenged statute empowers the State to act as a market participant—not a regulator—to achieve its goals, its activities under the Maine Rx Program are not limited by the dormant Commerce Clause.

A. The Maine Rx Program Does Not Regulate Out-of-State Transactions.

A state law affecting transactions occurring outside of its borders for products clearly destined for its market should not be treated as per se invalid unless the law has the same effect as a tariff—that is, if the law gives an advantage to the enacting state's industries or destroys a competitive edge enjoyed by out-of-state industries, or has the practical effect of regulating prices in other states' markets. *West Lynn Creamery*, 512 U.S. at 193 (1994); *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 528 (1935). The Maine Rx Program does neither.

The challenged statute does not regulate manufacturer-distributor transactions, be they in-state or out-of-state. Instead, the law empowers the State to negotiate voluntary rebates from manufacturers when their products are sold at the retail level to Maine consumers who enroll in the Maine Rx Program.[4] Whether any given manufacturer-distributor transaction remains the same or changes, nothing on the face of the Maine Rx law makes it do either. "[A] statute has extraterritorial reach when it necessarily requires out-of-state commerce to be conducted according to in-state terms." *Cotto Waxo Co. v. Williams*, 46 F.3d 790, 794 (8th Cir. 1995) (finding that Minnesota statute prohibiting the sale of a product did not violate the interstate commerce clause). Like the Minnesota statute at issue in *Cotto Waxo*, the Maine statute is indifferent to the terms of manufacturer sales to distributors, or where those sales occur.

The rebates negotiated under the Maine Rx law do not necessarily change the price that a wholesaler pays a

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[4] Petitioner likening the statute's effects to a duty also ignores the voluntary character of the program and the negotiating process toward participation. Participation by manufacturers is not mandatory. It is worth noting that Petitioner did not bring a claim that the Maine statute violates the Constitutional prohibition on states imposing a duty.

manufacturer for its products or otherwise dictate any terms of the transaction. In fact, the record is devoid of any evidence to support a conclusion as to any effect on the price or profitability of manufacturer-wholesaler transactions. Increased market share may actually improve the profitability of a manufacturer that negotiates a Maine Rx rebate with the State, at the expense of a manufacturer that does not, or it may have no effect whatsoever. *See PhRMA*, 249 F.3d at 97 (Keeton, J., concurring); Andrew S. Kruliwich, *The Response to Health Care Reform by the Pharmaceutical Industry*, 50 Food & Drug L.J. 1, 4 (1995). It is not the role of the courts to speculate whether a manufacturer's profits may be adversely affected, nor does the Commerce Clause extend a constitutional protection to the profitability or market share of any individual manufacturer. *See Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127 (1978) (holding there is no Commerce Clause violation "simply because an otherwise valid regulation causes some business to shift from one interstate supplier to another").

Manufacturer-distributor sales of prescription drugs are just one link in the chain of commerce of products bound for the Maine market. Where those initial sales take place is irrelevant to any dormant Commerce Clause analysis, so long as all comparable transactions are treated equally. *See, e.g., Consolidated Cigar Corp. v. Reilly*, 218 F.3d 30, 55-58 (1st Cir. 2000) (upholding cigar advertising regulations to the extent that they are limited to the Massachusetts market, despite impact on out-of-state manufacturers); *Association of Int'l Auto. Mfgs. v. Abrams*, 84 F.3d 602, 612 (2nd Cir. 1996) (New York law requiring vehicle "bumper quality" stickers affecting out-of-state manufacturers not a per se violation of the Commerce Clause); *Toy Mfrs. of Am. v. Blumenthal*, 986 F.2d 615 (2nd Cir. 1992) (holding that state law requiring toy safety labels is not per se invalid despite effect on out-of-state manufacturers); *State of New York v. Brown*, 721 F. Supp. 629, 638-640 (D.N.J. 1989) (upholding New Jersey milk

pricing scheme despite effect on producer-distributor sales taking place in New York).

To hold otherwise would be to "allow manufacturers to avoid state regulation, under the guise of Commerce Clause protection, through marketing decisions that the manufacturers themselves create, promote, and control." *Lorillard Tobacco Co. v. Reilly*, 84 F. Supp. 2d 180, 199-200 (D. Mass. 2000), *aff'd in part and rev'd in part on other grounds, Consolidated Cigar Corp.*, 218 F.3d 30; *see also Brown*, 721 F. Supp. at 640 n.11 (stating that Court should not encourage "subterfuge" of permitting milk producers to evade New Jersey regulations by transferring ownership of milk products in New York). Indeed, some of the nation's largest prescription drug manufacturers, including SmithKline Beecham and Bristol-Myers Squibb, switched from in-state distributors to out-of-state distributors in anticipation of this litigation. *See Drug Maker Fires Back at Maine*, New York Times, Aug. 4, 2000 (First Cir. Amici App. at 131); Ed Silverman, *Maine's Radical Rx: Rural State Finds Itself Front and Center in a National Debate*, Newark Star Ledger, Oct. 8, 2000 (First Cir. Amici App. at 133).

In essence, out-of-state drug manufacturers sending their products to Maine for retail sale seek to use the Commerce Clause to secure more favorable treatment than a manufacturer located within Maine would be entitled to under the Maine Rx law. The manufacturers have conceded that the statute can constitutionally reach in-state manufacturers and even out-of-state manufacturers who sell to in-state distributors, absent any illegal benchmarking. Transcript, Hearing on Preliminary Injunction (D. Me., Oct. 19, 2000) (J. A. at 189-90). What the manufacturers seek, then, is immunity from state regulation based solely upon the situs of their transactions with distributors. Such a rigid interpretation of the dormant Commerce Clause would enable manufacturers to evade the otherwise valid exercise of a

state's authority to protect the health and welfare of its citizenry, and should not be tolerated.

Similarly, there is no evidence in the record to suggest that the Maine Rx law will have the effect of controlling prescription drug prices charged to consumers in other states. Maine's statute is easily distinguished form the Illinois law at issue in *Edgar v. Mite*, 457 U.S. 624, 642 (1982), that directly regulated business takeovers occurring outside the state; the Connecticut statute in *Healy v. Beer Institute*, 491 U.S. 324, 337-38 (1989) that prevented brewers from competitively pricing their products in Massachusetts; the New York statute in *Brown-Forman Distillers Corp., v. New York State Liquor Auth.*, 476 U.S. 573, 582 (1986), that prevented distillers who had posted prices in New York from changing their price elsewhere; or the New York statute in *Baldwin*, 294 U.S. at 521 (1935), that projected its legislation into Vermont by regulating the price to be paid for milk acquired there.

Neither is there any tying of the prices charged in Maine to the Medicaid price. The Commissioner is instructed by the statute only to use his "best efforts" to negotiate an initial rebate "equal to or greater than the rebate calculated under the Medicaid program," and later rebates "equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government." 22 M.R.S.A. §2681 (4)(B) and (C). Best efforts to negotiate do not rise to the level of price-tying.

The manufacturers' real concern here is not a burden, or a risk of a burden, to interstate commerce, either by Maine alone or by the several states through differing legislation. The "evil" perceived by the manufacturers is that other states will conclude, as has Maine, that it is within their ability and interest to use their buying power to negotiate lower

prescription drug costs for their most vulnerable residents. *Cf. Exxon Corp.*, 437 U.S. at 128.[5]

Given the evenhanded approach of the Maine Rx statute, the Court should apply a lower level of scrutiny—if any—under the dormant Commerce Clause. Using the balancing test set forth in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), the First Circuit correctly concluded that the State's substantial interest in "provid[ing] prescription drugs to Maine citizens who could not otherwise afford them" clearly outweighs any incidental effects the law may have on "manufacturers' possible loss of profits." *PhRMA*, 249 F.3d at 84; *see also Gary D. Peake Excavating, Inc. v. Town Board of Hancock*, 93 F.3d 68, 76 (2nd Cir. 1996) (stating that "[l]egislation pertaining to public health and safety consistently has been recognized as an important local interest").

B. The Maine Rx Law Empowers the State to Act as a Market Participant, Not a Market Regulator.

The lower courts need not have subjected the Maine Rx Program to analysis under the dormant Commerce Clause. The statutory provisions at issue here are exempt from Commerce Clause scrutiny because they empower the State to act as a market participant, not a market regulator, in order to achieve its laudable goals. Maine has long provided pharmaceutical benefits and pharmaceutical benefits management, directly and indirectly, for large segments of its citizenry, such as low-income residents and state employees, and the Maine Rx Program simply expands upon Maine's participation in the market to cover uninsured citizens who affirmatively choose to enroll in the new benefits plan. By

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[5] Petitioners did not argue in any court below that the Maine Rx Program discriminates against interstate commerce. *PhRMA*, 249 F.3d at 83. It is well established that absent the most extraordinary circumstances, legal theories not raised in any court cannot be broached for the first time on appeal. *Paterson*, 491 U.S. at 185.

empowering the State to negotiate price discounts and rebates for Maine Rx participants, and to use the threat of prior authorization under the State's Medicaid program to leverage better price rebates, the Act merely enables the State to engage in the same market behavior that private PBMs can and do use in their own commercial transactions on a regular basis.

The Commerce Clause provides "no indication of a constitutional plan to limit the ability of the states themselves to operate freely in the free market." *Reeves, Inc. v. Stake*, 447 U.S. 429, 437 (1980). Instead, the Supreme Court has "ma[d]e clear that if a State is acting as a market participant, rather than a market regulator, the dormant Commerce Clause places no limitation on its activities." *South Central Timber Dev. v. Wunnicke*, 467 U.S. 82, 93 (1984); *see also Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794 (1976); *White v. Massachusetts Council of Constr. Employers*, 460 U.S. 204 (1983). To do otherwise would infringe upon "state sovereignty [and] the role of each State as guardian and trustee for its people," *White*, 460 U.S. at 207 n.3 (internal quotations omitted), and interfere with our federalist system in which "'a single courageous State may, if its citizens choose, serve as a laboratory and try novel social and economic experiments'" to solve compelling local problems. *Reeves*, 447 U.S. at 441, quoting *New State Ice. Co. v. Liebmann*, 285 U.S. 262 (1932) (Brandeis, J., dissenting).

The only relevant inquiry then is "whether the challenged 'program consitute[s] direct state participation in the market.'" *White*, 460 U.S. at 208, quoting *Reeves*, 447 U.S. at 436 n.7. That market must be "relatively narrowly defined" and constitute "'a discrete, identifiable class of economic activity in which [the State] is a major participant.'" *Wunnicke*, 467 U.S. at 97, (quoting *White*, 460 U.S. at 211 n.7; *see also National Foreign Trade Council v. Natsios*, 181 F.3d 38, 63 (1st Cir. 1999)). Furthermore, to remain on sure footing, the State's role within that market

should be limited to activities "equally available to a private party," *Rockville Centre v. Hempstead*, 196 F.3d 395, 401 (2nd Cir. 1999), and of the type commonly engaged in by private actors in that market. *See Wunnicke*, 467 U.S. at 96 (State exceeded market participant role in state timber sales by imposing contract restrictions on post-sale matters that sellers usually have no say over in the commercial context); *Natsios*, 181 F.3d at 65 ("The proper inquiry is whether [the State] is acting as an ordinary market participant would act . . . ."); *Rockville Centre*, 196 F.3d at 399 (contract restrictions imposed by municipality were "not uncommon in private transactions").

The rebate negotiation and prior authorization provisions of the Maine Rx Program clearly fit the bill. The challenged statute empowers the State to expand its long-standing participation in the discrete market of pharmaceutical benefits management services and to use its market leverage to obtain better prescription drug prices for Maine Rx enrollees. Maine, like most other states, already provides this service for statutorily defined populations. The State serves as a benefits manager for needy citizens through the Medicaid program, 22 M.R.S.A. §§3174-M and 3174-R, and for other disadvantaged, elderly or disabled citizens through the Elderly Low-Cost Drug Program, 22 M.R.S.A. §254. The Maine Rx Program extends the State's role as a PBM to another segment of Maine residents—the uninsured and underinsured—in response to a present and growing health care crisis.

With the advent of managed care, PBMs are now widely used in both the private and the public sector to assist in the purchase of prescription drugs at more advantageous prices than would otherwise be available to individual consumers or the medical plans that purchase their drugs. The PBMs obtain lower prices by negotiating rebates from drug manufacturers and/or lower reimbursement rates from retail pharmacies.

Although a modern phenomenon, PBMs operate within market principles in a classic "middle-man" role between buyers and sellers. PBMs typically contract with large employers, health maintenance organizations and other group plans to manage and administer their pharmaceutical benefits. Their control over access to large numbers of patients, and their ability to shift the market share of drugs through prior authorization lists, various types of formularies and incentives, gives the PBMs the influence they need to negotiate significant rebates from drug manufacturers. "The success of PBMs has resulted largely from their success in using consolidated purchasing power to secure rebates and discounts from drug manufacturers. . . . Drug manufacturers know that PBMs control a substantial proportion of their market share and that it is crucial to be listed favorably on the PBMs' formularies." Arnold J. Rosoff, *The Changing Face of Pharmacy Benefits Management*, 42 St. Louis U.L.J. 1, 23 (1998). "In other words, [PBMs] permit the manufacturers to make up in volume what they are losing in price." Andrew S. Kruliwich, *The Response to Health Care Reform*, 50 Food & Drug L.J. at 4 (1995).[6]

The challenged statute hews closely to the private PBM market model. The Maine Rx law expressly authorizes the State to act as a "pharmacy benefit manager" on behalf of those residents who elect to participate by enrolling in a Maine Rx consumer card program.[7] 22 M.R.S.A. §2681 (unnumbered introductory paragraph), (1), (2)(F) and (5); *see also PhRMA*, 249 F.3d at 90-91 (Keeton, J., concurring). As with a PBM in the private sector, the State negotiates with manufacturers for rebates *to itself* based on purchases by

[6] For more detail on PBMs and how they operate, *see* First Cir. Amici App. at 032-112.

[7] While enrollment is open to all Maine residents, only those residents without adequate private or government prescription drug health insurance coverage will benefit by participating.

Maine residents who enroll. 22 M.R.S.A. §2681(2)-(4). The State contracts directly with the manufacturers for the rebates that they will provide. The State then establishes discounted prices for participating pharmacies and reimburses pharmacists on a regular basis using funds from the manufacturer rebates. *Id.* at §2681(5) and (6).

In performing those functions, the State incurs substantial costs and puts its fiscal resources on the line. It advances substantial capital to cover the "float" for customer discounts, incurs the risk of manufacturers' breaches, pays processing fees to pharmacists and administers a complex web of transactions to complete the chain of price discounts, manufacturer rebates and pharmacy reimbursements.[8] *See* 22 M.R.S.A. §2681(6), (8-14). In short, the State acts just like a private-sector PBM, performing the same middle-man functions, only for a clientele that is underserved by the private market.[9] In that sense, the Maine Rx program "has substantially enlarged the market," both by expanding the role of PBMs in Maine and increasing access to prescription drugs for people who could not otherwise afford them. *Alexandria Scrap*, 426 U.S. at 815 n.* (Stevens, J., concurring); *see also* Quirion Aff. ¶¶ 5-6 (Add. of First Cir.

[8] The Legislature appropriated more than $4.5 million to a dedicated fund that provides the working capital for the reimbursements and fees, in addition to appropriations to carry out the program. 2000 Me. Legis. Ch. 786 at Sec. A-7. The rebates from the manufacturers compensate the State for the amount paid to pharmacists for the discount, but not for the professional fees paid the pharmacists. 22 M.R.S.A. §2681(5) and (6).

[9] Because a PBM's ability to negotiate rebates is based on its market power, i.e., the number of consumers to whom it can control access for a manufacturer's drugs, some private PBMs have attempted to enroll uninsured, cash-paying customers—the same market targeted by the Maine Rx Program—in consumer card programs offering discounts on drugs. Robert DiChiara *et al., Tug-of-War Over Rebates,* American Druggist, May 1997, at 44 (First Cir. Amici App. at 032, 036.) However, manufacturers have resisted those efforts by excluding those consumer card programs from rebates. *Id.* (First Cir. Amici App. at 038).

Amici Brief at 2); Moran Aff. ¶¶ 5-6 (Add. of First Cir. Amici Brief at 6); Donahue Aff. ¶¶ 2-6 (Add. of First Cir. Amici Brief at 7-8).

As with a PBM in the private sector, the State's ability to effectively bargain for manufacturer rebates to finance price discounts for Maine Rx participants stems solely from its power to deliver, or threaten to affect, market share. Consistent with the use of preauthorization lists in the private sector, the statute authorizes the State as PBM to use its ability to control market share through the threatened use of prior authorization under one benefits plan, Medicaid, to leverage better benefits for Maine Rx participants, to the extent permitted by Medicaid law. 22 M.R.S.A. §2681(7). The State uses the same type of market mechanism under its Elderly Low-Cost Drug Program to obtain price discounts for qualified seniors. *Id.* at §254(8), (8-A).

The Maine Rx provisions at issue here mirror the market mechanisms used by all private PBMs to maximize their market power. Neither empowering the State to negotiate manufacturer rebates, nor adopting the market tool of prior authorization to leverage better deals for Maine Rx participants, involves any powers unavailable to private actors. The Maine Rx provisions at issue here do not permit the State to use judicial or administrative processes for injunctive relief, to impose civil fines, or to seek criminal penalties against recalcitrant manufacturers. Nor do they regulate the price of prescription drugs for non-participating consumers in Maine. Rather, the State simply proposes to extend its economic influence over market share as the benefits manager for the Medicaid outpatient drug program to include an additional pool of lives.[10] The manufacturers'

[10] The State adopted this market-participation approach after recalling from the Governor's desk initial legislation submitted in response to the crisis in prescription drug affordability for the uninsured. *Cf.* L.D. 2599 and Committee Amendment "A" (119th Legis. 2000) (proposing to establish a Fair Drug Pricing Board to set maximum manufacturer prices for prescription drugs) (First Cir. Amici App. at 1, 22). That legislation, embodying a more regulatory approach to the problem, was passed by the Legislature but ran into opposition from Governor Angus King, who was concerned about its constitutionality. After lengthy negotiations, a compromise was reached, and the bill was recalled from the Governor's desk and amended to its present form. 119th Me. Legis. Rec., 2nd Sess., (April 26 and 28, 2000) at S-2412 and S-2476 (First Cir. Amici App. at 113-114); Francis X. Quinn, *Compromise Unveiled on Prescription Drug Bill*, Associated Press, May 11, 2000 (First Cir. Amici App. at 129).

objection to the law, therefore, is in essence a complaint that Maine chooses with whom it will deal as a benefits manager, a choice characteristic of *any* market participant.

That the State has shouldered its PBM role in order to promote the public good, rather than to make a profit or obtain for itself some other economic benefit, does not change its status as a market participant. Both *Alexandria Scrap*, 426 U.S. 794, and *Reeves*, 447 U.S. 429, "involved situations in which states 'intended their entrances [into the market] to affect the flow of commerce so as to enhance public values.'" *Natsios*, 181 F.3d at 64, *quoting* Laurence Tribe, *Constitutional Choices* 144 (1985).

Nor is there any principled reason to arbitrarily restrict "the market participation exception to acts of buying or selling" goods. *Independent Charities of Am. v. Minnesota*, 82 F.3d 791, 799 (8th Cir. 1996). The Supreme Court has applied the market participation doctrine in settings where the State did not directly buy, sell or take title to goods, *see Alexandria Scrap*, 426 U.S. at 797 (finding market participation where State paid a "bounty" to private processors to encourage destruction of scrap vehicles), and where the relevant market was for services rather than tangible goods, *see White*, 460 U.S. at 211 n.7, 214 (finding participation in construction labor market, even where City was not the direct employer of construction workers or in privity of contract with affected private subcontractors). *See also Independent Charities of*

Am., 82 F.3d at 799 (State "participating in the charitable fund raising market" entitled to restrict access to its employees in the workplace); *Rockville Centre*, 196 F.3d at 398 (town engaged in waste disposal market entitled to impose contract restrictions on towns using its services); *Swin Resource Systems v. Lycoming County, Pa.*, 883 F.2d 245, 250 (3rd Cir. 1989) (county participating in waste disposal services market permitted to give preference to county customers); *Four T's, Inc. v. Little Rock Munic. Airport Comm'n*, 108 F.3d 909, 913 (8th Cir. 1997) (upholding concession fees where town was in the market of providing facilities for rental car services).

The Maine Rx law authorizes the State to engage in a discrete, identifiable class of economic activity that is equally available to private parties, and that poses no impediment to the flow of interstate commerce. When acting as market participants, states are entitled to the same "freedoms from federal constraints, including the inherent limits of the Commerce Clause," as are private enterprises. *Reeves*, 447 U.S. at 439. The manufacturers have failed to present any evidence that Maine's strategy of pooling its market power to negotiate rebates constitutes activity unavailable to a private party.

CONCLUSION

For all of the above reasons, the Court should affirm the decision by the First Circuit Court of Appeals and lift the District Court's order preliminarily enjoining the State of Maine from implementing its Maine Rx Program.

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IN THE
SUPREME COURT OF THE UNITED STATES

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Writ of Certiorari To The United States Court of Appeals For the First Circuit

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BRIEF *AMICI CURIAE* OF AARP, COMMUNITY CATALYST, FAMILIES USA AND THE MEDICARE RIGHTS CENTER IN SUPPORT OF RESPONDENTS

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Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF *AMICI CURIAE* OF AARP, COMMUNITY CATALYST, FAMILIES USA AND THE MEDICARE RIGHTS CENTER IN SUPPORT OF RESPONDENTS

STATEMENTS OF INTEREST[1]

AARP is a national, nonprofit, nonpartisan organization for people 50 and over with more than 35 million members. More

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[1] No counsel for any party authored any portion of this brief. No persons other than amici curiae, their members, or their counsel have made a monetary contribution to the preparation and submission of this brief. The written consents of the parties have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

than 192,000 members live in Maine. AARP supports state and national policy initiatives to broaden access to prescription drugs and to lower costs for medications. Because Medicare generally does not cover prescription drugs, AARP has been a strong supporter of state programs that broaden consumer access to affordable prescription drugs.

AARP in Maine advocated for passage of Maine's Act to Establish Fairer Pricing for Prescription Drugs (Maine Rx). Me. Rev. Stat. Ann. tit. 22, § 2681 (2001); 2000 Me. Legis. Serv. 786 (legislative history). AARP also supported the Pharmacy Drug Discount Program (PDDP) (known as Healthy Maine Prescriptions or HMP), a complementary program to Maine Rx which provides the Medicaid discount price to persons within 300% of the federal poverty threshold. AARP assisted in enrolling the more than 112,000 beneficiaries in Healthy Maine Prescriptions drug program. Thousands of Maine AARP members obtain medication through Healthy Maine Prescriptions, and many thousands more would participate in Maine Rx.

AARP has participated as *amicus curiae* in numerous recent cases involving state Medicaid prescription drug coverage, including filing briefs in support of Maine's Healthy Maine Prescriptions in *PhRMA v. Thompson*, 191 F. Supp.2d 48 (D.D.C. 2002), *appeal docketed*, No. 02-5110 (D.C. Cir. Mar. 29, 2002), and in support of Michigan in *PhRMA v. Michigan Dep't of Cmty. Health*, No. 238862 (Mich. Ct. App. argued Sept. 5, 2002). The latter case involves PhRMA's challenge to Michigan's attempt to contain drug costs in its Medicaid and other low-income prescription drug programs. AARP also is supporting numerous other states' pharmacy assistance programs providing coverage and/or reducing drug costs such as Oregon and Hawaii. Nationally, AARP is working for passage of a Medicare prescription drug benefit and AARP's "Check Up on Your Prescriptions" campaign encourages consumers to use medications wisely and safely, and to consider if lower cost generic drugs are appropriate for them.

Community Catalyst is a Boston-based national advocacy

organization that works in partnership with consumer and community groups around the country to promote health care justice. Community Catalyst seeks to strengthen the voice of consumers and communities wherever decisions shaping the future of our health system are being made. Community Catalyst provides a range of technical assistance services that includes policy analysis, legal assistance, strategic planning and community organizing support. Community Catalyst also builds coalitions among its constituencies on a range of issues, from hospital conversions and quality care to Medicaid expansions and prescription drug access.

Families USA is a national not-for-profit consumer advocacy organization that promotes policies to achieve high-quality, affordable health coverage for all Americans. Founded in 1982, Families USA has been and continues to be the leading voice for expanded health coverage to the uninsured and for low-income individuals and families. In support of this mission, Families USA has worked to strengthen the Medicaid and Medicare programs so that they are increasingly responsive to economically vulnerable individuals and families. Families USA also convenes and leads a broad coalition of consumer organizations that support and defend the continued viability of the Medicaid program. As an integral part of its mission, Families USA has developed and promoted policies that expand access to affordable prescription drugs for seniors and low-income families. Directly and through its support of health care advocacy groups nationwide, Families USA promotes programs designed to help individuals who lack prescription drug insurance to gain access to affordable medications. Families USA's interest in the Maine Rx Program directly stems from that program's goal of providing Maine residents with access to more affordable prescription drugs.

The Medicare Rights Center (MRC) is a national, consumer service organization that assists older and disabled Americans secure needed health care. MRC receives over 75,000 calls annually to its national and New York State consumer hotlines. Many MRC clients are struggling to pay for their health care, and MRC works with them to enroll in Medicaid and other assistance programs. By far, the most

common life-threatening health care need of MRC clients is their inability to afford drugs that their doctors prescribe. The Medicare Rights Center is leading a nation-wide campaign to bring the plight of older and disabled Americans who go without prescribed medication to the attention and conscience of the nation.

SUMMARY OF ARGUMENT

Amici Curiae, AARP, Community Catalyst, Families USA, and the Medicare Rights Center join together in supporting Maine Rx, a state program seeking to improve access to prescription drugs for the people of Maine. The prices of prescription drugs place many drugs beyond the reach of many of the residents of Maine. Medicaid is a state-federal cooperative program designed to assist people to get medically necessary health care, and Congress has expressly granted states the authority to implement prescription drug prior authorization in their Medicaid programs. 42 U.S.C. § 1396r-8(d). Maine's use of prior authorization to induce manufacturers to provide discounts to all residents, not just persons eligible for the basic Medicaid benefits, does not conflict with the intent of Congress in establishing Medicaid. Maine Rx is consistent with the best interests of Medicaid recipients because, by expanding access to medicines for the general population, Maine Rx will keep more people healthier longer so they are less likely to become eligible for Medicaid benefits and further deplete the limited resources of the Medicaid program.

Based on the record in this case, PhRMA is unable to demonstrate that Medicaid recipients are likely to suffer irreparable harm as a result of prior authorization. First, the use of an effectively implemented, clinically sound prior authorization requirement does not inevitably harm patients. Second, Maine already has a Medicaid prior authorization program independent of Maine Rx which has shown few problems thus far. And third, there is little basis to believe that physicians will abandon the medical welfare of their patients in the face of a properly run prior authorization system. Prior authorization may even serve the salutary effect of counter-balancing the heavy pressure on doctors to prescribe a

particular drug because of promotion by the drug companies rather than its distinct therapeutic advantages.

Prescription drugs have become an increasingly important part of health care. But the dramatic increase in their costs means that many people simply cannot obtain the drugs to improve the quality of their lives and in some cases even prolong them. Maine recognizes that the health and welfare of its residents depend upon access to these medicines, and, through Maine Rx, believes it has found a way to lower the costs by connecting voluntary discounts to a reasonable limitation in the Medicaid program. The First Circuit decision should be affirmed, and Maine Rx should be implemented so that whatever discounts the manufacturers can be persuaded to offer can start benefitting the health of the people of Maine.

ARGUM[illegible]

I. Introduction

Maine is a low-income state, ranking thirty-sixth in the nation in per capita income.[2] The high and rising costs of prescription drugs has made it difficult for the State to publicly finance prescription drug programs. The availability of dramatically lower priced prescription medications in nearby Canada highlights the problem of unaffordable medications for Maine citizens and policy makers alike, and is a principal impetus for Maine's history of experimenting with programs aimed at increasing access to prescription medications for its citizens. Stephen Crystal et al., AARP Public Policy Institute, *Three States' Approaches to Pharmaceutical Assistance: A Guide for the Perplexed* 34 (2002); Tara Parker-Pope, *The Ins and Outs of Getting Drugs (The Legal Kind) From Across the Border*, Wall St. J., Oct. 22, 2002, at D1 (for example, showing

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[2] In 1999, Maine had a per capita money income of $19,533, compared with a national per capita income of $21,587. U.S. Census Bureau, *State and County Quick Facts: Maine*, *at* http://quickfacts.census.gov/qfd/states/23000.html (last visited Nov. 5, 2002).

Tamoxifen, a breast cancer drug, is $287.15 in the U.S. for 90 pills (20 mg), but $47.38 in Canada; Celebrex, an arthritis drug, is $133.25 in the U.S. for 100 pills (100mg) and $68.21 in Canada – prices are in U.S. dollars.)

In 1975, Maine established one of the country's first pharmacy assistance programs, Low Cost Drugs for the Elderly and Disabled Program (DEL or Low Cost Drug). Eligibility is restricted to persons 62 years-of-age and older and disabled persons age 19 or older, with both groups allowed incomes no more than 185 percent of poverty ($16,391 for one person in 2002). DEL is a subsidy plan so that these beneficiaries can obtain medications to treat specified illnesses. *See* Maine Dep't of Human Servs., *Prescription Drug Assistance: A Guide to Programs and Benefits* (2002), *available at* http://www.state.me.us/dhs/beas/medbook.htm [hereinafter Prescription Drug Assistance]. DEL is entirely financed through state funds. Crystal, *supra*, at 48.

Maine's standard Medicaid program, Maine Care, provides prescription drug benefits to eligible individuals, generally only to children and their families, the elderly and disabled who are extremely poor. As of March of 2002, the income eligibility requirements are a gross monthly income under $813 and assets under $2,000, or a couple with a gross monthly income under $1,095 and assets under $3,000. Prescription Drug Assistance, *supra*. Finding that access to prescription drugs was still a critical problem for the rest of the people of Maine, the State recently established two pharmacy discount programs, Maine Rx and Healthy Maine Prescriptions. Healthy Maine is a Medicaid waiver program, established under section 1115 of the Social Security Act, which allows the state to conduct experimental projects which further the objectives of the Medicaid program. Me. Rev. Stat. Ann. tit. 22, § 258 (2001). Healthy Maine Prescriptions provides the Medicaid discount price to any Maine resident whose income is within 300% of the federal poverty threshold, and generally provides an average of 25% savings off retail drug prices. Prescription Drug Assistance, *supra*. Healthy Maine is also being challenged by PhRMA in *PhRMA v. Thompson, supra*.

Maine Rx is an innovative state program aimed at remedying the serious financial barriers to access for prescription drugs faced by many Maine residents who still have a problem affording medications yet whose incomes are not low enough to qualify for other prescription drug assistance programs. Maine Rx helps people obtain needed prescription drugs, drugs they do without when costs are too great.[3] Lowering the cost of drugs is one way to increase access so that consumers will fill the prescriptions their doctors have determined they need. Judge Keeton recognized that "many and probably most citizens of Maine who have a need for pharmacy products would not have adequate resources and practical means to get the pharmacy products they need absent the Maine Rx Program." *PhRMA v. Concannon*, 249 F.3d 66, 97 (1st Cir. 2001)(Keeton, J., concurring).

Maine Rx uses a prior authorization mechanism in its Medicaid program to encourage drug manufacturers to negotiate price rebates with Maine so that the State can lower the cost of drugs for all the people of the state. PhRMA argues that Maine Rx's use of prior authorization in its Medicaid program to leverage manufacturer participation in Maine Rx violates the Supremacy Clause of the United States Constitution because it conflicts with the Social Security Act, and that Maine Rx's rebate provision conflicts with the Commerce Clause. This brief will address only the question of whether Maine Rx's

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[3] A recent survey of eight states reports that nearly one quarter of all seniors said that they did not fill a prescription because it was too expensive or skipped doses of their medications to make them last longer. Even patients with severe and chronic conditions like heart disease and diabetes often go without medication because of costs. Kaiser Foundation et al., *Seniors and Prescription Drugs, Findings From a Survey of Seniors in Eight States* (July 2002). In a March 2002 national survey of Americans aged 45 or older, more than one in five (22%) reported they did not fill at least one prescription prescribed by their doctor during the last two years, with the cost of the drug being the main reason people cited for not getting their prescription filled. AARP, *Prescription Drug Use Among Persons Age 45+* 24-25 (June 2002). Of particular concern is that the proportion of people who say cost was a main reason for not getting a prescription is rising, up from 13% during a 1986 survey to 32% in 2002. *Id.* at 72.

attempt to bring down the cost of prescription drugs for all its people violates the Supremacy Clause.

II. Neither the Letter nor the Intent of the Social Security Act Prohibit a State from Using Medicaid Prior Authorization to Achieve Prescription Drug Savings.

Under the Supremacy Clause, a federal law may expressly or impliedly preempt state law. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992). The beginning assumption is that "the historic police powers of the States [are] not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress." *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)(citations omitted). This is especially true with co-operative federalism programs such as Medicaid. Where coordinate state and federal efforts exist within a complementary framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one. *N.Y. Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405 (1973).

PhRMA argues that Maine's use of prior authorization in its Medicaid program impliedly conflicts with the Social Security Act despite the Act's expressed authorization of state prior authorization programs for any pharmaceutical benefit it provides. 42 U.S.C. § 1396r-8(d)("A State may subject to prior authorization any covered outpatient drug.") Their argument stretches implied conflict preemption far beyond any precedent of this Court. PhRMA cites no court decision holding anything analogous, other than the district court decision reversed by the First Circuit. Precedent aside, PhRMA argues that Maine Rx must be struck down even before it is implemented because prior authorization necessarily creates such a burden on Medicaid beneficiaries that it conflicts with the object and purpose of Congress in enacting Medicaid.

Far from conflicting with congressional intent, Maine Rx is consistent with long-standing Congressional concern with the costs of prescription drugs and the corresponding burden on publicly financed health care coverage. In 1990, Congress

recognized that it had to do something about the costs of prescription drug to the Medicaid program. Medicaid is one of the largest purchasers of drug manufacturers' products -- if the not the largest -- yet the manufacturers were routinely charging Medicaid more than what they charged other large drug purchasers. H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. Congress established a rebate requirement for manufacturers who participate in Medicaid, allowing state Medicaid programs to use their positions as a huge purchaser of the manufacturers' products to require manufacturers to reduce their profits.
42 U.S.C. § 1396r-8 (a)(1)(2002)("In order for payment to be available . . . [under Medicaid] the manufacturer must have entered into and have in effect a rebate agreement . . . with the Secretary, on behalf of States.") The goal was to allow Medicaid programs to reduce the prices of prescription drugs.

At the same time, Congress permitted individual state programs to choose certain other methods to control costs of providing prescription drugs. For example, states can restrict or exclude entire classes of drugs, limit quantities, or impose prior authorization as a condition of coverage. *See* 42 U.S.C. § 1396r-8(d)("Limitations on coverage of drugs.") Congress made sure that when a state chooses to require prior authorization, it must do so in a fashion that does not harm Medicaid beneficiaries. State programs must provide fast responses to authorization requests and dispense a three day supply of the requested drug in an emergency situation.
42 U.S.C. § 1396r-8(d)(1)(A) and (d)(5).[4]

Much has been made of the fact that Maine is attempting to use Medicaid prior authorization to assist all its people with

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[4] Maine must also comply with other Medicaid requirements designed to assure beneficiaries efficiently receive good quality health care, such as promptly furnishing health care, 42 U.S.C. §1396a(a)(8); timely providing the beneficiary with notice and hearing rights upon reductions, terminations and denial of care, 42 U.S.C § 1396a(a)(3); and assuring that care and services are available to Medicaid beneficiaries at least to the extent that those services are available to the general population, 42 U.S.C. § 1396a(a)(30)(A).

drug c sts, not just the poorest of the poor who are eligible for all of the state's Medicaid benefits. Because Maine is using the authority given it by Congress to use prior authorization in its Medicaid program to help those who are beyond the financial eligibility limits of basic Medicaid, both PhRMA and the Solicitor General argue it does not serve the interests of the Medicaid program. (Pet'r Br. at 26; United States Br. Supp. Reversal at 10.)

The purpose of the Medicaid program is to provide health care to those in need, therefore, Maine's attempt to expand access to health care does not contradict Congressional intent. Maine Rx is entirely consistent with the Medicaid provisions of the Social Security Act; nothing in the Act prohibits either pharmacy discount programs, or states from expanding Medicaid coverage. Providing pharmacy discounts serves Medicaid's objective to furnish medical assistance on behalf of families with dependant children, and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services. 42 U.S.C. § 1396 (2002). Maine Rx simply increases the number of persons eligible to receive the benefit of a discount obtained through the State's efforts to furnish medical assistance -- in this case, access to pharmaceuticals.

As a practical matter, the enrollees in Maine Rx most likely to benefit from the program are the population most sensitive to the high costs of prescription medications-- lower income persons, without prescription drug coverage insurance or the means to purchase prescription drugs, such as the 40% of Medicare beneficiaries with annual incomes below $10,000 who lacked prescription drug coverage in the fall of 1999. David Gross, AARP Public Policy Institute, *Medicare Beneficiaries and Prescription Drugs: Costs and Coverage* (2002), *available at* http://reasearch.aarp.org/health/dd77_rx.html. The Maine Legislature passed Maine Rx "to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare." Me. Rev. Stat. Ann. tit. 22,

§ 2681 (2001). The First Circuit recognized that this goal was consistent with Medicaid: "The Maine Rx Program will potentially provide prescription drugs to Maine citizens who could not otherwise afford them." *Concannon*, 249 F.3d at 84.

Medicaid benefits are not restricted to a static population subject to a uniform set of eligibility requirements, such as those persons who meet the low income and resources standards of Supplemental Security Income (SSI).[5] There are many state programs which utilize the Medicaid program to expand health care assistance beyond the group it traditionally covers. While state Medicaid programs must provide coverage to individuals receiving cash assistance through the Temporary Assistance for Needy Families (formerly AFDC) or SSI, states can elect to provide Medicaid coverage to "medically needy" individuals whose incomes exceed state established income levels. 42 U.S.C § 1396a(a)(10)(C) (2002). Maine has a medically needy program under which children, elderly, or disabled with very high medical bills can become eligible for services by spending enough of their income on health care to meet a state established income limit.[6] In addition, as of 1989, States participating in the Medicaid program were required to pay Medicare premiums and cost sharing amounts for certain low income Medicare beneficiaries whose income exceeded SSI eligibility levels. 42 U.S.C. §§1396a(a)(10)(E)(i); 1396d(p) (2002).

States can also use a variety of mechanisms such as waivers, like Maine has done with the Healthy Maine program discussed earlier, to cover broader populations and provide

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[5] In 2002, in order to be eligible for SSI, a single person could earn no more than $780 per month, with a $2,000 resources limitation. U.S. Soc. Sec. Admin., *Fact Sheet: Social Security, available at* http://www.ssa.gov/pressoffice/colafacts2003.htm (last visited Nov. 5, 2002).

[6] The provision of the Maine Medicaid program, known as MaineCare, that establishes the medically needy category of eligibility can be found at CODE ME. R. §10-144-332.1100 (2002). The income requirements are covered in § 10-144-332.2450.

additional services. *See* Medicaid home and community based waivers (§1915(c) of the Social Security Act codified at 42 U.S.C. § 1396n (2002)); "Freedom of choice" waivers (§ 1915(b)of the Social Security Act codified at 42 U.S.C. § 1396n (2002)) and "research and demonstration" waivers (§ 1115 of the Social Security Act codified at 42 U.S.C. § 1315 (2002). Under these provisions, states can request the Secretary of Health and Human Services waive certain federal requirements in the general Medicaid program so that they can provide health care benefits which may provide different services, use a more generous financial eligibility criteria, or provide benefits to a particular group which are not provided to all Medicaid beneficiaries. *See, i.e.,* 42 U.S.C. §1396a(a)(10)(B) (2002) (relating to comparability of service requirements). "Waivers are intended to provide flexibility needed to enable States to try new or different approaches to the efficient or cost effective delivery of health care services, or to adapt their programs to the special needs of particular areas or groups of recipients." 42 C.F.R. §430.25(b) (2002).

Extending care to persons in need beyond just the poorest of the poor is a long-standing purpose of the Medicaid program. There are many more examples of this, but a recent study summarizing the Medicaid enrollment data from the states demonstrates "that Medicaid continues to evolve from a welfare-based program to a more traditional health insurance program." Kaiser Comm'n on Medicaid and the Uninsured, *Report on Medicaid Enrollment in 50 States: December 2001 Data Update* (Oct. 2002) *available at* http://www.kff.content/2002/4067/4067.pdf.

Maine Rx allows the Commissioner, if he is successful in his negotiations with drug manufacturers, to provide a discount for Maine residents who need to purchase prescription drugs. Such discounts help those whose income is above current eligibility levels for all Medicaid's benefits, but it also serves the interest of the Maine's Medicaid program as a whole, as is further described below. Lowering the cost of the prescriptions means that more people can afford health-sustaining medications and prevents their health from deteriorating to the point that those persons become financially eligible for

Medicaid benefits. This acts to preserve limited Medicaid funds for those already eligible. See *Concannon*, 249 F.3d at 76-77 (citing evidence on the limited record before it showing Maine Rx may reduce Medicaid expenditures). Moreover, the Medicaid program itself will save money when clinically appropriate, less expensive drugs are prescribed over more expensive drugs with no therapeutic advantage through an effectively implemented prior authorization program.[7]

III. Maine Rx is Consistent with the Best Interests of Medicaid Recipients.

The Medicaid statute directs states to consider the "best interests" of Medicaid beneficiaries. State plans must "assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best

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[7] Maine should thoughtfully and effectively implement its prior authorization program because all Medicaid recipients must have efficient access to all medically necessary prescription drugs. Maine Rx has not yet been implemented, but Commissioner Concannon has attested that the Maine Department of Human Services will assure that Medicaid beneficiaries receive all medically necessary medications. *Concannon*, 249 F.3d at 76. Given Maine's history of attempting to expand access to prescription drugs, see discussion *supra* at 5-6, there is no reason to doubt Maine official's assertions. Moreover, Maine provides protection in the prior authorization program beyond federal requirements. While federal law only requires that a 72-hour supply of medicine be dispensed in an emergency situation, Maine is more generous, authorizing the pharmacist to provide a 96-hour supply of the prescribed drug whenever the Department is unable to promptly respond to the prior authorization request. *See* Maine Dep't of Human Servs., MaineCare Benefits Manual, 10-144, ch. 101 § 80.07-3, *available at* http://www.state.me.us/sos/cec/rcn/apa/10/ch101.htm. Commissioner Concannon has also given pharmacists the ability to "provide a one-time fill of a 34-day supply prior to establishing medical necessity via the prior authorization process." (Letter from Kevin W. Concannon to Ronald Preston, Associate Regional Administrator, Division of Medicaid and State Operations of Oct. 31, 2002, at 3.) *See* Lodging of *Amicus Curiae* Maine Citizen Leadership Fund.

interests of the recipients." 42 U.S.C. § 1396a(a)(19) (2002). PhRMA argues that this provision is violated because some unidentified and unknown number of people may encounter obstacles in receiving "first-choice" prescription drugs because of a prior authorization requirement. (Pet'r Br. at 17.) However, both the First and Eleventh Circuits have considered the best interests language and determined it to be directed at the state's Medicaid program as a whole, not to its individual recipients.

The First Circuit decided that Maine Rx furthered Medicaid purposes because making prescription drugs more accessible to the uninsured and underinsured may reduce Maine's Medicaid expenditures by keeping people healthier longer so they do not ultimately end up using more costly Medicaid services. *Concannon*, 249 F.3d at 76. The Eleventh Circuit recently upheld a prior authorization program in Florida's Medicaid program, concluding that the Florida law "operates to drive down the cost of prescription drugs under the Medicaid program by providing drug manufacturers with strong economic incentives to offer the state supplemental rebate.... By stretching its Medicaid dollars, the Florida law has the potential for providing more and better medical services to its target population." *PhRMA v. Meadows*, No. 02-10151, 2002 U.S. App. LEXIS 18487, at *31-31, 304 F.3d 1197 (11th Cir. Sept. 6, 2002). *Cf. Harris v. James*, 127 F.3d 993, 1010 (11th Cir. 1997) (finding §1396a(A)(19) imposes a generalized duty on the States and is insufficiently specific to confer any particular rights on a plaintiff, and citing other similar cases). Protecting the program as a whole is the only way to ultimately protect the program for the individual, particularly when states face budget crises and are forced to cut eligibility and services as described below.

A. The Burden and Costs of Prescription Drugs Show Why So Many Maine Residents are in Need of Medical Assistance to Pay for Them, and Why it is in Medicaid's Interest to Assist Them.

Prescription drug costs are becoming the major strain on publicly funded insurance programs as drug costs are the fastest

growing component of health care, rising 15% or more per year over the past several years. Nat'l Inst. for Health Care Mgmt. Research & Educ. Found., *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* 2 (2002), *available at* http://www.nihcm.org/spending2001.pdf. A key factor in rising drug costs is rising drug prices. According to the National Institute for Health Care Management, roughly one-third of the increase in drug costs is attributable to rising drug prices. *Id.* at 3. Prices have a disproportionate impact on those individuals who lack coverage for prescription drugs. In fact, in calendar year 2001, the prices of the 50 drugs most commonly prescribed for seniors, increased three times the rate of inflation. *See* Families USA, *Bitter Pill: The Rising Prices of Prescription Drugs for Older Americans* (June 2002), *available at* http://www.familiesusa.org/BitterPillreport.pdf. These price increases are reflective of a long standing trend of rising drug prices. This same study found that prices for the 50 drugs most commonly prescribed for seniors, increased at rates far faster than inflation over the last 5 years and the last 10 years. *Id.* One of the main goals of the Maine Rx Program is to moderate these price increases and ameliorate the impact of these rising prices for those individuals who lack coverage.

Not only are rising prescription drug costs a strain on individuals, they are also placing a tremendous strain on publicly funded programs such as Medicaid. The Medicaid program is a vitally important source of drug coverage for low-income disadvantaged people nationwide, paying for approximately 14 percent of prescriptions written in the U.S. in 2000. *See* Brian K. Bruen, Kaiser Comm'n on Medicaid and the Uninsured, *States Strive to Limit Medicaid Expenditures for Prescribed Drugs* 2 (Feb. 2002), *available at* http://www.kff.org/content/2002/20020213/4030.pdf. Medicaid spent $16.6 billion of federal and state funds on outpatient drugs in 2000; that figure does not include what was spent in Medicaid managed care plans, or hospitals or other settings where drugs are included in the total payment for services. *Id.* at 3. Older persons and persons with disabilities accounted for 80 percent of Medicaid drug spending in 1998. Kaiser Comm'n on Medicaid and the Uninsured, *Medicaid and Prescription Drugs: An Overview* (Oct. 2000), *at* http://www.kff.org/

content/2001/1609/ 1609.pdf.

Medicaid programs are under great pressure to reduce coverage and services due to soaring costs and budget pressures.[8] In fiscal year 2002, state spending on Medicaid increased 11 percent. *See* Kaiser Survey, *supra* note 8, at 15. Medicaid programs are stressed not only by the rising costs for current beneficiaries, but also by the increasing number of persons being driven into poverty and therefore becoming eligible for Medicaid. The poverty rate in 2001 rose for the first time since 1991-1992, reaching 32.9 million persons or 11.7% of the population, up from 11.3% in 2000. Bernadette

[8] The vast majority of states are facing significant budget shortfalls. *See* Kaiser Comm'n on Medicaid and the Uninsured, *State Budgets Under Stress: How are States Planning to Reduce the Growth in Medicaid Costs?* (July 2002) [hereinafter Kaiser State Budget Report]; Nat'l Ass'n of State Budget Officers, *NASBO Analysis: Medicaid to Stress State Budgets Severely in Fiscal 2003* (March 15, 2002). In an effort to control Medicaid expenditures, states are reducing benefits and restricting Medicaid eligibility criteria, cost containment strategies that eliminate health care for Medicaid beneficiaries. *See* Kaiser State Budget Report, *supra*, at 23-5; Amy Goldstein, *States' Budget Woes Fuel Medicaid Cuts: Poor Lose Coverage and Services*, Wash. Post, Oct. 11, 2002, at A01. Missouri, for example, cut over 30,000 people from Medicaid by lowering the threshold at which parents become eligible. Vernon Smith, PhD, et al., Kaiser Comm'n on Medicaid and the Uninsured, *Medicaid Spending Growth: Results From a 2002 Survey* 25 (Sept. 2002), *available at* http://www.kff.org/content/2002/4064/4064.pdf [hereinafter Kaiser Survey]. Massachusetts is eliminating coverage for approximately 50,000 long-term unemployed individuals and Nebraska is enacting eligibility cuts that will cause 12% of the state's total Medicaid enrollees to lose eligibility. *Id.* In fact, 18 states are planning eligibility cuts or restrictions for 2003, up from eight states restricting eligibility in 2002. *Id.* Meanwhile, the number of states making Medicaid benefit reductions is increasing. After nine states reduced benefits in fiscal year 2002, 15 states have passed benefit reductions for 2003. *Id.* at 24. Thirteen states have reduced long term care; cuts include shutting down nursing homes and instituting new reimbursement methodologies. *Id.* States are also reducing benefits through copays, increased cost sharing, managed care expansions, and increased disease management programs. *Id.*

D. Proctor & Joseph Dallaker, U.S. Census Bureau, P60-219, *Poverty in the United States: 2001* 2 (Sept. 2002), *available at* http://www.census.gov/prod/2002pubs/p60-219.pdf.[9] The number of uninsured also rose in 2001 to 41.2 million people or 14.6% of the population up from 14.2 % in 2000. Robert J. Mills, U.S. Census Bureau, P60-220, *Current Population Reports, Health Insurance Coverage: 2001* 2 (Sept. 2002), *available at* http://www.census.gov/prod/2002pubs/p60-220.pdf. Concomitant with the increase in poverty and decrease in insurance coverage, is an increase in the number of persons on Medicaid. The percentage of people covered by Medicaid rose from 10.6 % in 2000 to 11.2 % in 2001. *Id.*

Medicaid budgets simply cannot sustain prescription drug prices rising at current rates, and in many states the result has been, and will continue to be, program cuts. The objectives of the Medicaid Act are served when states reduce prescription drug costs expanding access, not when they are forced to cut benefits and eligibility for Medicaid programs. Limiting access for effective drugs puts frail, low-income, elderly patients at increased risk of institutionalization in nursing homes and may actually increase Medicaid costs. S.B. Soumerai et al., *Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*, 325 New Eng. J. Med. 1072 (1991). Most of these patients once admitted to nursing homes never returned to the community. *Id.* Other research by these authors found that limits on coverage for the costs of mental health medication resulted in sharp increases in the use of emergency mental health services and partial hospitalizations. S.B. Soumerai et al., *Effects of Limiting Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services By Patients With Schizophrenia*, 331 New Eng. J. Med. 650 (1994). The authors concluded that in addition to increasing the use of acute mental health services

[9] The poverty threshold is $8,494 for a single person 65 years of age and older and $9,214 for a person under 65. *Id.* at 5. Maine's household median income fell 5.9% in 2000-2001 from the previous two-year period. Carmen DeNavas-Walt & Robert W. Cleveland, U.S. Census Bureau, P60-218, *Money Income in the United States: 2001* 11 (Sept. 2002), *available at* http://www.census.gov/prod/2002pubs/p60-218.pdf.

among low-income patients with chronic mental illnesses, limits on coverage for the costs of prescription drugs also increased costs to the government and caused pain and suffering on the part of the patients. *Id.* Therefore, increasing access to effective prescription drugs -- both within the Medicaid program and the general population -- will save money for the Medicaid program as a whole.

States reported that the most significant factor contributing to higher Medicaid spending was the increasing costs of prescription drugs. Bruen, *supra*, at 15. Forty-four states cited prescription drugs among the three most significant factors driving Medicaid costs, with 25 states ranking prescription drugs as the single most significant factor behind increased Medicaid spending. *Id.* at 16. With the costs of drugs being so high, this is an area where States are looking to cut. The survey of Medicaid officials in all 50 states and the District of Columbia revealed that, in fiscal year 2003, 40 states plan to implement prescription drug cost controls, up from 32 states in FY 2002. *Id.* at 4. Cost containment controls such as prior authorization requirements are one way states are contending with increasing Medicaid costs. In fact, in fiscal year 2003, 23 state Medicaid programs plan to place more prescription drugs under prior authorization. *Id.* at 23. Maine can, and already is, doing the same. When Maine, acting as a pharmacy benefits manager for the entire population, leverages its buying power in the Medicaid program to bring down the costs for everyone, thereby facilitating greater access to medicines, its entire population is healthier and therefore less likely to incur the illnesses that will require them to need the resources of an already overburdened Medicaid program.

IV. The Evidence that Individual Medicaid Beneficiaries will Suffer Actual Harm from Maine Rx's Reasonable Limitations on So-Called First-Choice Rx Drugs is Insufficient to Support an Injunction.

PhRMA argues that creating an obstacle to "first-choice drugs" constitutes a harm to Medicaid beneficiaries sufficient to warrant an injunction against the implementation of Maine Rx. (Pet'r Br. at 5.) But that argument fails because PhRMA is

unable to show that the obstacle of prior authorization will result in irreparable harm to Medicaid beneficiaries. "A facial challenge to a legislative act is of course the most difficult challenge to mount successfully since the challenger must establish that no set of circumstance exist under which the act would be valid." *United States v. Salerno*, 482 U.S. 739, 745 (1987). "The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute." *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982). The First Circuit correctly concluded that dueling affidavits and other materials in the record fell short of establishing that the Act will inflict inevitable or even probable harm on Medicaid patients. *Concannon*, 249 F.3d at 77-78.[10]

PhRMA's argument presupposes that whenever so-called first-choice drugs face the need for prior authorization beneficiaries will be harmed, and further assumes that physicians will fail to advocate for clinically appropriate drugs for their patients. Prior authorization does not inevitably or necessarily harm Medicaid beneficiaries, and doctors can work with an effectively administered prior authorization program to assure Medicaid beneficiaries receive medically appropriate drugs.

A. Prior Authorization Does Not Inevitably Harm Patients.

1. Studies have shown that prior authorization can be implemented without resulting in adverse clinical outcomes.

A large study in an urban teaching hospital found no adverse effects on clinical outcomes as a result of prior authorization requirements for selected drugs. A. Clinton

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[10] PhRMA argues that there is actual harm to Medicaid recipients despite the fact that Maine Rx has never been implemented by citing the dispensing limitation (four drugs) in the Florida prior authorization program, and arguing that problems there demonstrates harm to Maine Medicaid beneficiaries. Maine Rx does not contain a dispensing limitation– a feature that apparently does cause problems with access to drugs.

White, Jr., et al., *Effects of Requiring Prior Authorization for Selected Antimicrobials: Expenditures, Susceptibilities, and Clinical Outcomes,* 25 Clinical Infectious Diseases 230 (1997) (concluding that requiring prior authorization of selected antimicrobial drugs can decrease expenditures and improve susceptibilities to antibiotics without compromising patient outcomes or length of hospital stay.) A study of the Tennessee Medicaid program's implementation of a prior authorization requirement for non-generic nonsteroidal anti-inflammatory drugs found a 53% decrease in expenditures for NSAID prescriptions, with no concomitant increase in Medicaid expenditure for other medical care. Walter E. Smalley, M.D., et al., *Effect of Prior-Authorization Requirement on the Use of Nonsteriodal Anti-inflammatory Drugs by Medicaid Patients*, 332 New Eng. J. of Med. 1612 (1995).

The studies do not establish by any means that prior authorization can never cause problems for a particular patient, but do show that prior authorization programs do not inevitably or even probably result in harmful clinical outcomes.

2. Maine's existing prior authorization program has not caused many problems with access to prescription medications.

Since 2001, Maine has subjected some prescription drugs to prior authorization under the authority of 42 U.S.C. § 1396r-8(d) and has data on its implementation. During the most recently analyzed period, January to September 2002, Maine filled more than 3.3 million prescriptions through the Medicaid program. Kevin W. Concannon, *Perspectives on Promoting the Appropriate Use of Pharmaceuticals, at* http://www.oregonrx.org/Ogrxpdf/Governor's%20Conference%20presentations%20PDF/Commisioner_OREGON_Revision_20021001.pdf (last visited Nov. 5, 2002). During that period, Maine's Medicaid program had 31,169 requests for prior authorization, or .94 percent of the total number of prescriptions. Ninety-three percent were approved, with an average determination time of 2.08 hours. *Id.* Ninety one percent of the requests were determined within 24 hours. *Id.* Less than one tenth of one percent, or 2,182, of

the total Medicaid prescriptions were unapproved, and a number were unapproved because of insufficient data for determinations such as incorrect NDC codes, ineligible patients, and absent or insufficient clinical support. *Id.* A grievance or fair hearing process should ensure that the remaining disputes are resolved in a manner that ensures beneficiaries obtain medically necessary drugs.

B. Physicians Will Not Abandon the Medical Welfare of their Patients in the Face of Prior Authorization Requirements.

1. Physicians are knowledgeable about prior authorization systems because they are extensively utilized in the health care system.

Because doctors are familiar with prior authorization programs, Maine's expansion of prior authorization in its Medicaid program will not inexorably lead to harm for its Medicaid beneficiaries. "The percentage of employers using prior authorization programs to manage access to specific drugs has increased every year since PBMI [Pharmacy Benefit Management Institute] first asked about its use. In 1996, 43% of employers used prior authorization programs; in 2000, that number increased to 77%." Inst. Mgmt. & Admin., *In Perspective*, Managing Benefits Plans 7 (Mar. 2002). Eighty-two percent of HMO plans used prior drug authorization in 2000. Joseph Eichenholz, *Trends in Managed Care Pharmacy: Responding to Changing Environments*, 8 J. Managed Care Pharmacy 104 (Mar./Apr. 2002).

As PhRMA phrases it, the law "forc[es] the physician to choose between a first-choice drug that requires prior authorization and second-choice, possibly less effective drug, that does not." (Pet'r Br. at 15.) That supposition does not rise to the level of demonstrating an inevitable conflict with the best interests of Medicaid recipients. For any given Medicaid beneficiary, no one knows what would be a "first-choice drug." The first choice may be one which does not require prior authorization. And if a first choice drug does require prior approval, if it is superior for that patient, the physician can

request it. If a drug requiring prior authorization is first-choice for any reason other than for that particular patient it is medically superior, then substitution will not harm the Medicaid beneficiary.

Substitution itself is not necessarily harmful, although for any particular patient there may be clinical reasons a specific drug is better. But with respect to the medical need for a specific drug, perception may not be reality. For example, the Food and Drug Administration (FDA) recognizes that simply because generic drugs cost less money, many people falsely perceive them as less effective than more expensive name brand medications. FDA, *FDA Ensures Equivalence of Generic Drugs, at* http://www.fda.gov/cder/about/whatwedo/testtube-17.pdf ("Generic drugs contain exactly the same active ingredients as the brand-name drug and are just as safe and effective.") The reality is that if there is a generic available for a name brand medication, it must be bio equivalent in that it performs in the same manner. *Id.*

A pharmacist sums up generic switching for brand names:

> Making unnecessary switches for economic motives only that end up causing adverse effects for patients or actually cost the health care system more in other costs because of greater use of system resources elsewhere . . . should be avoided in every instance. It would be foolish and harmful to argue against real cases where patients are hurt by switches. But, in reality, few cases have been published suggesting problems despite the millions of prescriptions filled with generic equivalents annually.

John E. Murphy, PharmD, *Generic Substitution and Optimal Patient Care*, 159 Archives Internal Med. 429 (1999).

Maine's prior authorization requirement will undoubtedly force the doctors to make informed prescription choices among

therapeutically equivalent drugs.[11] Savings are achieved when doctors determine that there is no medical reason to prescribe a drug requiring preauthorization. These are the kinds of clinical judgments entrusted to physicians every day. There is no basis on this record to believe that physicians in Maine will prescribe less effective therapies for their patients because Maine requires them to think about which drugs they are prescribing. Educating medical providers about how to obtain necessary medications and ensuring an efficient state administrative process are issues that go to the implementation of a prior authorization program, not grounds for concluding that it is necessarily against the best interests of patients.

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[11] The House Report accompanying H.R. 5835, the legislation which eventually became the prescription drug prior authorization provision of the Social Security Act, recognized the tension between prior authorization and physician discretion, stating:

> As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care. However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements -- i.e., assuring access by Medical beneficiaries to prescription drugs where medically necessary.

H.R. Rep. 101-881 at 98 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2110. Congress clearly understood that prior authorization has the potential to limit coverage, but that as long as beneficiaries get medically necessary drugs, it is an acceptable limitation.

2. Drug promotion activities influence prescribing patterns.

Indeed, prior authorization requirements may serve to counter-balance the heavy pressure put on physicians to prescribe a particular drug, not because of its therapeutic advantages, but rather because of promotion by the drug companies. While the link between drug promotion and prescriber behavior is not yet well understood, one survey found that 71 percent of family physicians believe that direct-to-consumer ("DTC") advertising pressures physicians into prescribing drugs that they would not ordinarily prescribe. Martin S. Lipsky, MD, & Christine A. Taylor, *The Opinions and Experiences of Family Physicians Regarding Direct-to-Consumer Advertising,* 45 J. Fam. Pract. 495, 497 (1997). There is at least a suggestion that DTC campaigns may result in increased prescribing for certain drugs. Promotional spending directed at consumers has increased significantly. Richard Frank, PhD, et al., Kaiser Family Foundation, *Trends in Direct-to-Consumer Advertising of Prescription Drugs*, (Feb. 2002)(finding a nine-fold increase in DTC advertising between 1994 and 2000). There "is strong circumstantial evidence that sales of the three prescription oral antihistamine drugs Claritin, Allegra and Zyrtec – all approved in the early to mid 1990s – have been substantially boosted by heavy DTC ad campaigns from 1998 to 2000." Steven D. Findlay, Nat'l Inst. for Health Care Mgmt. Research & Educ. Found., *DTC Advertising: Is it Helping or Hurting?* 3 (Sept. 10, 2002)(statement before the Federal Trade Commission health care workshop). Unfortunately, prescriptions driven by patient demand or based on promotional information may not always be the most appropriate choice; "previous findings [demonstrate] that demand by patients is the most common reason offered by physicians for inappropriate prescribing." Meredith B. Rosenthal, PhD, et. al., *Promotion of Prescription Drugs to Consumers* 346 N. Eng. J. Med. 498, 503 (2002)(citing Schwartz, et al., *Physician Motivations for Nonscientific Drug Prescribing*, 28 Soc. Sci. Med. 577-82 (1989)). In addition, there is evidence that many drug promotions are not balanced or accurate. Sidney M. Wolfe, MD, *Direct-To-Consumer Advertising – Education or Emotion Promotion?* 346 N. Eng.

J. Med. 524, 526 (2002)(suggesting that "confusion arises when commercially driven promotional information is represented as educational.")

An FDA survey found that when patients asked their doctor about a drug, 48% received a prescription for that medication. Kathryn J. Aikin, PhD, FDA, *Direct-to-Consumer Advertising of Prescription Drugs: Preliminary Patient Survey Results* (Apr. 18, 2002), *available at* http://www.fda.gov/cder/ddmac/DTCnational2002a/sld040.htm. Moreover, for patients who asked about a specific brand, 69% received a script compared to 41% of those who asked about more general treatment.

In 2001, pharmaceutical companies spent $4.7 billion on physician detailing (the term of art for promotion of drugs to physicians) and over $2 billion on educational events aimed at physicians. Findlay, *supra*. Manufacturers also provided physicians with $10 billion worth of free samples to give patients and spent $2.8 billion direct-to-consumer marketing. *Id.* PhRMA keenly appreciates the fact that prior authorization may cause doctors to choose one drug over another, causing a potential of loss of sales for a drug that requires prior authorization yet is not clinically superior to one that does not require prior authorization. But harm to a patient would only occur if his or her physician refused to prescribe medically necessary drugs.

Amici believe the answer is to educate physicians, the public and administrators of the appropriateness of particular drugs for particular medical problems and the need to have a good system in place -- not prohibit a State from using its Medicaid prior authorization program to achieve savings for all its residents.

CONCLUSION

Maine's attempt to expand access to medically necessary drugs to all of its residents by using its prior authorization authority in Medicaid does not on its face conflict with the Medicaid program. Maine has continually attempted to

broaden, not diminish, access to prescription drugs for its residents. The First Circuit's decision on the question of Medicaid preemption should be affirmed, and Maine Rx should be implemented.

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No. 01-188

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF OF THE STATES OF MASSACHUSETTS, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, HAWAII, INDIANA, IOWA, KENTUCKY, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, OKLAHOMA, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, VERMONT, WASHINGTON, WEST VIRGINIA AND COMMONWEALTH OF PUERTO RICO AS AMICI CURIAE SUPPORTING RESPONDENTS

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QUESTIONS PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. § 1396 *et seq.*, prohibits a state from using authority under that statute to secure rebates from drug manufacturers for drugs sold to uninsured Maine residents?

2. Whether the Maine Rx statute, 22 Me. Rev. Stat. Ann. § 2681 *et seq.*, which seeks rebate payments in connection with in-state retail sales of prescription drugs to uninsured Maine residents, violates the dormant Commerce Clause because wholesale transactions in those drugs occur outside of Maine?

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INTEREST OF THE AMICI CURIAE

Amici curiae submit this brief in support of respondents Kevin Concannon, Commissioner, Maine Department of Human Services, and G. Steven Rowe, the Attorney General of Maine.

The issues posed in this case have significant implications for the States' ability to address the health care needs of their citizens, an area of traditional State concern and authority. The advent of effective pharmaceutical therapy for numerous chronic and acute medical conditions has created an opportunity to extend the lives and alleviate the suffering of millions of patients. But as the prices for these disease-sparing and often life-saving products skyrocket, and as new but also more expensive drugs are developed, a large number of persons have become unable to afford good health.[1]

The amici States have a strong interest in assuring their citizens effective access to necessary medical care. As prescription drugs have become an increasingly critical component of medical care and a significant and growing part of the cost of care, the amici States have developed

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[1] Spending on prescription drugs has increased by 15% or more per year in recent years (17.1% from 2000 to 2001). The bulk of this increase reflects escalating prices and the shift to higher cost drugs. While drug spending represents about 10% of overall health care spending, it has accounted for almost a third of the increase in health care costs over the past five years. Office of the Actuary, *2000 National Health Expenditures, Chart: The Nation's Health Dollar: 2000*, http://www.hcfa.gov/stats/nhe-oact/tables/chart.htm. It is expected that prescription drug spending will continue to rise in the 10-15% range. *Express Scripts 2001 Drug Trend Report*, www.express-scripts.com.

prescription drug initiatives and/or support development of such initiatives to ensure the availability of drugs to persons who need them. The States have a strong interest in ensuring the availability of prescription drugs to their uninsured citizens, the majority of whom are low-income individuals,[2] including those ineligible for benefits under the Medicaid Program, 42 U.S.C. § 1396 *et seq.* ("Medicaid"), and/or elderly persons without drug coverage under the Medicare Program, 42 U.S.C. § 1395 *et seq.*[3] This interest is particularly acute given the lack of federal action to provide affordable prescription drugs to the uninsured.

The amici States strongly support the efforts of Maine to protect the health and welfare of its uninsured citizens through its Act to Establish Fairer Pricing for Prescription

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[2] March 2002 Report of the Kaiser Family Foundation, Kaiser Commission on Medicaid and the Uninsured, "The Uninsured: A Primer, Key Facts About Americans Without Health Insurance," at 2 (almost two-thirds of the non-elderly uninsured are low-income individuals or come from low-income families making less than 200% of the federal poverty level).

[3] Medicaid, operating under State statutes and funded jointly by the federal and State governments, does not require coverage for drugs; while all States have chosen to pay for prescription drugs, eligibility is limited. Original Medicare, the federal health program for the elderly, generally provides no coverage for prescription drugs in the outpatient setting. Nor is there any comprehensive federal program for people who are not eligible for Medicaid and find prescription drugs unaffordable. An estimated 23% of persons under 65 and 27% over 65 have no insurance for prescription drugs. David H. Kreling, et al., *Prescription Drug Trends: A Chartbook Update*, Menlo Park, CA: Kaiser Family Foundation (2001).

Drugs, 22 Me. Rev. Stat. Ann. § 2681 *et seq.* ("Maine Rx law" or "Maine Rx"), which seeks to extend to the uninsured pricing advantages already available to those enrolled in government programs or covered by private health plans. The disparity between retail prices–the prices paid by those least able to afford prescription drugs–and the drugs' lowest prices is significant: persons without insurance pay 123% more than the Veterans Administration Price and over 65% more than the Medicaid price.[4] Drug prices in the United States are substantially higher than drug prices abroad: 50% more than prices in Canada and Great Britain, 70% more than prices in France, 90% more than prices in Italy.[5]

States thus increasingly see their most vulnerable citizens face unacceptable choices–the elderly, for example, may be forced to choose between food or shelter and medication, may jeopardize their health by splitting medications to extend supply, or may even feel compelled to travel out of the country to seek access to cheaper drugs abroad. While Petitioner claims to represent the interests of Medicaid beneficiaries, its members' pricing practices

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[4] William H. von Oehsen, III, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*, Public Health Institute (2001), at 9.

[5] Alan Sager and Deborah Socolar, *A Prescription Drug Peace Treaty*, Health Reform Program, Boston University School of Public Health (2000), at 16. The drug industry has been the most profitable in the United States, as measured by median return on revenue, for each of the last ten years; during this period, the industry's profitability was one and a half times the next highest industry and nearly four times the median. *Profiting from Pain: Where Prescription Drug Dollars Go*, Families USA Publication No. 02-015, www.familiesusa.org (2002), at 13-14.

contribute directly to the impoverishment that forces vulnerable persons into the Medicaid Program. The States, by contrast, have a real and strong interest in protecting both their Medicaid beneficiaries and those whose health and welfare may be endangered by diminished access to necessary medical care.

Given the severity and immediacy of the problem at the local level, the States have taken the lead in efforts to make prescription drugs more affordable and available for their citizens. Some of these efforts involve law enforcement, combating attempts by pharmaceutical companies to maintain artificially high prices by improperly seeking to extend patents and through collusive agreements with competitors not to produce generic equivalents of brand-name drugs.[6] Others, like Maine Rx, are legislative or regulatory and are designed to serve populations whose needs are best known to the States themselves.

A number of States, including Maine, have enacted or proposed laws that provide discounted drugs to uninsured persons using negotiated manufacturer rebates. As explained by the Solicitor General, U.S. Br. 32-37, several of these programs involve formal agreements between States and the

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[6] *E.g.*, *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (alleged collusive agreement between brand-name and generic manufacturers to delay market entry of generic drug); *In re Buspirone Antitrust Litigation*, MDL No. 1410 (S.D.N.Y. filed Feb. 20, 2002)(alleged improper attempts by brand-name manufacturer to "evergreen" patent so as to block generic competition);*Ohio v. Bristol-Myers Squibb Co.*, No. 1:02CV01080 (D.D.C. filed June 4, 2002)(allegations that brand-name manufacturer excluded generic competition in part through enforcement of patents procured by fraud on the Patent Office).

Secretary of the U.S. Department of Health and Human Services ("Secretary") to extend benefits and/or eligibility under State Medicaid Programs. These programs represent important cooperative efforts between the federal and State governments, and the amici States support the efforts of the Secretary in advancing these programs. But these are not the only programs underway at the State level,[7] and the States have a particularly strong interest in ensuring that their authority to act in this area is not inappropriately limited by misapplication of federal law. While there is no single solution to the problem of affordable drugs, effective responses are more likely to emerge if States retain flexibility to enact a variety of different and innovative measures and to test a number of conventional and unconventional alternatives.

The States also have a strong interest in implementing Medicaid's stated purpose: to enable States to provide medical assistance to families and individuals who cannot afford care. The Maine Rx law increases access to drugs for uninsured[8] Maine residents, including low income persons and families who make up the bulk of the uninsured in Maine

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[7] *E.g.*, some States have enacted or proposed creation of State or multi-State purchasing cooperatives to increase market leverage. Still other States have enacted or proposed laws directly regulating the activities of pharmaceutical sales representatives and industry detailers. Some States have proposed price controls or maximum prices on prescription drugs. For information concerning State initiatives, *see generally* www.ncsl.org/programs/health/drugdisc02.htm.

[8] The implementing regulations limit the Maine Rx law's benefits to persons who have "no other reimbursement option available." (J.A. 317)

and elsewhere, thus promoting Medicaid's intended purpose. It does so in a manner permitted by federal law and consistent with the welfare of existing Medicaid beneficiaries. Of great significance to the amici States, Medicaid beneficiaries will continue to receive all necessary medications, as Congress intended. There is no frustration of Medicaid's purpose. There is, however, a significant health benefit to uninsured Maine residents.

SUMMARY OF THE ARGUMENT

The Maine Rx law addresses the health and welfare of Maine citizens and is presumed valid under the Supremacy Clause. Congress has not expressly preempted the law, nor has it occupied the field. The purpose of Medicaid is to enable the States to provide medical assistance in a cost-effective manner to needy persons. The Maine Rx law and regulations are written and intended to ensure that Medicaid beneficiaries receive all medically necessary medications. There is no harm to Medicaid recipients, and no conflict with Medicaid. An "actual conflict", on a facial challenge, is one that will necessarily occur in all cases.

Under the Supremacy Clause, there is no requirement that a non-conflicting State law promote federal purposes. But the Maine Rx law advances what Congress said was its purpose in enacting Medicaid–to enable the States to make medical care available to those who need it and cannot afford it. The Maine law further advances what the Solicitor General and federal Centers for Medicare & Medicaid Services ("CMS") acknowledge is a Medicaid purpose: increasing the availability of drugs to financially needy

individuals not eligible for Medicaid.[9] The Maine Rx law also serves an additional State purpose, to provide increased accessibility to residents who do not have insurance; it is plausible, on a facial challenge, to find that the bulk of the Maine Rx law benefits will go to low income persons and thus that the Maine law's principal purpose is also a Medicaid purpose, but nothing in the Supremacy Clause prevents a State law from advancing both federal and State purposes.

The Maine Rx law does not protect in-state commerce or affect competition in commerce. Nor does it control behavior in other States. Maine does not dictate the terms on which buyers and sellers do business outside the State, and it does not set the price of any out-of-state transaction. Drug manufacturers subject to the Maine Rx law may sell drugs in any other State at any price–Maine does not know or care what the out-of-state prices are. The fact that drug manufacturers are located outside Maine is completely incidental to the purpose and effect of the Maine Rx law, which would be exactly the same if all the manufacturers were located within Maine. The Maine Rx law is not an unconstitutional regulation of interstate commerce.

ARGUMENT

I. THE MAINE Rx LAW IS NOT PREEMPTED BY MEDICAID.

Under the Supremacy Clause, Congress may preempt State laws either explicitly or by occupying a field. When

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[9] Letter from Dennis G. Smith, Director of CMS's Center for Medicaid and State Operations ("CMS Director")(Sept. 18, 2002), attached to U.S. Br. at 46a *et seq*.

State law and federal law conflict, federal law governs. But the States do not make law at the discretion of the federal government, and absent explicit or field preemption, there is no requirement that non-conflicting State laws further federal purposes, even in areas where there might otherwise be federal interests. This principle is embodied in the Tenth Amendment–all powers neither delegated to the federal government nor prohibited to the States "are reserved to the States, respectively, or to the people."

While the Federal/State balance is partly the result of historical forces whose resolution produced the constitutional model, the system also reflects the imperatives of problem-solving in the real world. Federal rules address national problems. Local rules deal with local problems; local institutions are more adept at identifying and solving such problems. Local problems can be severe, "and state governments, in cooperation with the Federal Government, must be allowed considerable latitude in attempting their resolution." *New York State Department of Social Services v. Dublino*, 413 U.S. 405, 413 (1975).

A. The Presumption Against Preemption of State Health Care Laws.

Health care has traditionally been viewed as a local problem and State legislation related to health care as a State function. "The historic police powers of the State include the regulation of matters of health and safety." *DeBuono v. NYSA-ILA Medical and Clinical Services Fund*, 520 U.S. 806, 814 (1997). The Maine Rx law addresses health care, an area of traditional State concern.

The Court has stated many times that "where 'federal law is said to bar state action in fields of traditional state regulation...we have worked on the "assumption that the

historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *California Division of Labor Standards Enforcement v. Dillingham Construction, NA, Inc.* 519 U.S. 316, 325 (1997) (citations omitted). The "starting presumption [is] that Congress does not intend to supplant state law." *New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654 (1995).[10]

DeBuono, *Dillingham*, and *Travelers* are all decisions addressing ERISA, a law in which Congress explicitly stated an intention to preempt certain State law. The presumption must be even more cogent where Congress has not stated any intention to preempt.

B. There Is No Explicit or Field Preemption.

The Court has identified three forms of preemption under the Supremacy Clause. Preemption may be explicit: Congress "may preempt state authority by so stating in express terms." *Pacific Gas & Elec. Co. v. State Energy Resources Conservationand Development Comm'n*, 461 U.S. 190, 203 (1983). Medicaid contains no explicit statement of preemption.

Preemption may also be implied by the breadth of federal involvement; in such "field" preemption, "'the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same

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[10] State concern with health care may be contrasted with areas of peculiarly federal concern, *e.g.*, foreign affairs. *See, e.g., Hines v. Davidowitz*, 312 U.S. 52, 68 (1941). In such areas, "[a]ny concurrent state power that may exist is restricted to the narrowest of limits...."

subject.'" *Id., quoting from Fidelity Federal Savings & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982). In enacting Medicaid, Congress did not occupy the field. On the contrary, Congress explicitly intended the States to legislate in this area. Medicaid is "a cooperative federal/state program," U.S. Br. 2, and "every state in the nation currently operates its own Medicaid program under its own statutes." *Pharmaceutical Research & Manufacturers of America v. Meadows*, 2002 WL 31000006 (11th Cir. 2002). State Medicaid laws are diverse, and State Medicaid plans are not uniform. "States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances." U.S. Br. 3.

C. The Supremacy Clause Does Not Require State Laws to Further Federal Aims.

Only the third form of preemption, conflict preemption, is pertinent here. Conflict preemption arises when State law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Pacific Gas*, 461 U.S. at 204, *quoting Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).[11]

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[11] Conflict preemption may also arise if "compliance with both federal and state regulations is a physical impossibility." *Pacific Gas*, 461 U.S. at 204, *quoting Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). There is no claim that coexistence of the Maine Rx law and Medicaid is "physically impossible," and the Solicitor General acknowledges that State laws that "invoke the Act's prior authorization provisions to enable non-Medicaid recipients to obtain more affordable drugs" are not prohibited by Medicaid. U.S. Br. at 30.

To strike down a conflicting law, there must be an "actual conflict" between State and federal law. The Court "has observed repeatedly that preemption is ordinarily not to be implied absent an 'actual conflict.'... The 'teaching of this Court's decisions...enjoins seeking out conflicts between state and federal regulation where none clearly exists.'" *English v. General Electric Co.*, 496 U.S. 72, 90 (1990) (citations omitted). On a facial challenge, the conflict between State and federal law must be a necessary and not simply a possible outcome: the State law must "require or authorize conduct that *necessarily* constitutes a violation" of federal law "*in all cases*." *Rice v. Norman Williams Co.*, 458 U.S. 654, 661 (1982) (emphasis added).[12] Or, conversely, no "set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987). Any "possible set of ... conditions not pre-empted by federal law is sufficient to rebuff [the] facial challenge...." *California Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572, 589 (1988).

The Supremacy Clause does not require non-conflicting State laws to promote federal interests. Absent actual conflict, the States are free to enact their own laws and advance their own purposes–this is indeed, a basic tenet of federalism. *Dublino*, 413 U.S. at 413. Nor does conflict

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[12] "A high threshold must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act. Any conflict must be 'irreconcilable... The existence of hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute.'" *Gade v. National Solid Waste Mgmt. Ass'n*, 505 U.S. 88, 110 (1992), *quoting Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (Kennedy, J., concurring in part and concurring in judgment).

preemption turn on whether a State law is "within the scope of the broad discretion that Congress afforded the states." U.S. Br. 17. In *Dublino,* on which the Solicitor General relies for this statement, the Court explicitly rejected "the contention that pre-emption is to be inferred merely from the comprehensive character" of the federal law. 413 U.S. at 415. Indeed, the Court emphasized that "'clear manifestation of (congressional) intention'... must exist before a federal statute is held 'to supersede the exercise' of state action,'" *id.* at 417 (citation omitted), and that "[t]his Court has repeatedly refused to void state statutory programs, absent congressional intent to pre-empt them." *Id.* at 413. The Court explained that "'[i]f Congress is authorized to act in a field, it should manifest its intention clearly. It will not be presumed that a federal statute was intended to supersede the exercise of the power of the state unless there is a clear manifestation of intention to do so.'" *Id.* (citation omitted). The Court did not evaluate the "discretion" Congress afforded the State, nor did it prohibit the State from advancing its own purpose–indeed, it explicitly found that "[t]o the extent that the [State] rules embody New York's attempt to promote self-reliance and civic responsibility... and to cope with the fiscal hardships enveloping many state and local governments, this Court should not lightly interfere." *Id.* at 413. Congress may "manifest its intention" to supercede State law, but if it does not, States are free to enact laws promoting their own purposes.

D. The Maine Rx Law Does Not Conflict with Medicaid

1. The Purpose of Medicaid. Congress enacted the Medicaid program to enable "each State, as far as practicable under the conditions in such State, to

furnish...medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396. The States have wide flexibility in designing "medical assistance" provided under the State plans. *See, e.g., Alexander v. Choate,* 469 U.S. 287 (1985). Medicaid does not require the States to pay for prescription drugs. 42 U.S.C. § 1396d(a)(12). The purpose of Medicaid is not to provide all possible benefits to eligible recipients, but to provide "medical assistance."

Congress expressly permitted States choosing to pay for Medicaid prescription drugs to "subject to prior authorization any covered outpatient drug." 42 U.S.C. § 1396r-8(d).[13] There is no limitation in Medicaid on the number or identity of drugs subject to prior authorization. Nor is there any limitation on a State's motive or rationale in subjecting a drug to prior authorization.[14]

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[13] It also permitted States to establish formularies, lists of drugs approved for inclusion in (but not necessarily payment by) a State's Medicaid Program, 42 U.S.C. § 1396r-8(d)(4)(C). The formulary provision, adopted in 1993, provides that any excluded drugs must be subjected to a prior authorization program. 42 U.S.C. § 1396r-8(d)(4)(D).

[14] The only restrictions Congress placed on prior authorization were intended to ensure that delay would not affect the ability of patients to obtain medically necessary drugs. This was accomplished by requiring prior authorization programs to "provide[] response by telephone or other telecommunication device within 24 hours of a request for prior authorization" and "provide[] for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation."

Thus, it is not Medicaid's purpose to supply all prescription drugs or any specific drugs. It is not the purpose of Medicaid to provide recipients with drugs that are "paid for by Medicaid without reservation." Pet. Br. 16.[15] Medicaid's purpose is to provide "medical assistance"–to "ensure access...to prescription drugs where medically necessary." H.R. Rep. No. 101-881 (1990), at 98; Pet. Br. 23. Providing medically necessary drugs is the "best interest" of recipients required by Medicaid. 42 U.S.C. § 1396a(a)(19).[16]

OBRA 1990 made clear that the States may "require prior authorization with respect to any of the prescription drugs which they elect to cover" and "the bill would not affect any authority States have under current law to impose prior authorization controls on prescription drugs." 42 U.S.C. § 1396r-8(d); H.R. Rep. No. 101-881 at 95, 98.[17] Thus, while Congress "requir[ed] states to cover all drugs of participating manufacturers," Pet. Br. 23–and, of course, the Maine Rx law does not affect the coverage or participation in Medicaid of any drug–it did not limit the States' ability to "cover" any drug subject to prior authorization for any reason. OBRA 1990 created not a "delicate balance" of entitlements and limitations, Pet. Br. 23, but a condition precedent to participation of any drug in Medicaid–provision of a rebate. There is no entitlement to sell drugs free from prior authorization, and there is no limit on the States' ability to subject a participating drug to prior authorization.

2. The Maine Rx Law. The Maine Rx law "was enacted because of the Maine Legislature's concern that many Maine citizens who were not Medicaid recipients could not afford necessary prescription drugs." 249 F.3d 66, 71. The program is open to all State residents, *id.*; the implementing rules limit the discounts to individuals who do not have "other reimbursement option[s] available." (J.A. 317)

The regulations provide that drugs from manufacturers not providing rebates to Maine Rx will be subject to prior authorization only when clinically appropriate, and that Medicaid patients "shall be assured access to all medically necessary outpatient drugs." (J.A. 320) An advisory board comprised of physicians and pharmacists

> will make the final determination of the clinical appropriateness of any recommendation that a prior authorization requirement be imposed with respect to a particular prescription drug manufactured by a

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42 U.S.C. § 1396r-8(d)(1)(A), (d)(5).

[15] Nor is it the purpose of Medicaid to provide so-called "first choice" drugs. (J.A. 150). Indeed, such drugs may not be the safest and most effective in all situations. *Id.* Further, by choosing the more expensive of two equally effective drugs, a physician's "first choice" may harm the Medicaid program by reducing its ability to purchase other needed drugs.

[16] The reference in Medicaid to "consisten[cy] with simplicity of administration and the best interests of recipients" does not create an entitlement to "first choice" or extensively promoted drugs; given the prior authorization and formulary provisions and Congress's stated intention to "ensure access...to prescription drugs when medically necessary," H.R. Rep. No. 101-881 at 98, State laws that provide access to medically necessary drugs–and limit access to other drugs–are consistent with "simplicity of administration and the best interests of recipients."

[17] Before 1990 the States had "routinely required prior authorization for prescription or dispensing of drugs." U.S. Br. 19.

> manufacturer which has not entered into a Maine Rx Rebate Agreement. In making its determination of whether or not a prior authorization requirement is clinically appropriate, the DUR Committee shall be guided by the law of Medicaid, and particularly the principle that Medicaid recipients shall be assured access to all medically necessary prescription drugs.

(J.A. 167) *See Dublino,* 413 U.S. at 421 (the State "has attempted to operate the [State] rules in such a manner as to avoid friction" with federal law). "[D]etermination of whether a particular drug should be subjected to prior authorization requirement will be based firmly upon considerations of medical necessity." (J.A. 149)

While Petitioner does not explicitly accuse the Maine Rx law of impairing the health of Medicaid recipients, its brief is replete with references to "[h]olding Medicaid patients hostage", "threaten[ing] Congress' intended beneficiaries", "risks with Medicaid patients health", "ransom", and "burden", Pet. Br. 2, 13, 14, *passim,* references that suggest harm to individuals that, if the Maine law is implemented as written and intended, will not occur. No beneficiary will be injured. No one will be denied access to medically necessary drugs.

3. There is No "Actual Conflict" Between the Maine Rx Law and Medicaid. Medicaid's purpose is to enable the States to provide "medical assistance" in a cost-effective manner to those who cannot afford necessary medical care. Under Maine Rx, the State of Maine provides medical assistance to uninsured persons and assures Medicaid recipients "access to all medically necessary prescription drugs." (J.A. 167) There is no conflict with Medicaid's purpose.

When a drug is unique or medically necessary, the beneficiary will receive the drug, and Petitioner's relevant member will receive payment. (J.A. 149) When there are a number of identical or medically comparable drugs, however, subjecting one to prior authorization may result in disappointing sales for its manufacturer (it may also increase sales for a competitor). But Medicaid does not guarantee sales of a particular manufacturer's drug. It does not guarantee that a drug manufacturer will be able to sell its drug to the State without prior authorization. Nor is it the purpose of Medicaid to provide "unrestricted" access to drugs. So long as the beneficiary receives medically appropriate drugs, Medicaid's purpose is accomplished.

To find preemption on a facial challenge, the Maine Rx law must "necessarily" conflict with Medicaid "in all cases." *Rice v. Norman Williams Co.,* 458 U.S. at 661. Petitioner argues that there is a "serious risk" that persons confronted with prior authorization may go without needed drugs. Pet. Br. 6. But this is not a *necessary* outcome. And it is not an intended outcome–the law and the "regulations as written"[18] state that prior authorization will be consistent with therapeutic requirements, and Medicaid recipients will always receive medically necessary drugs. Since it is both intended and plausible that the Maine Rx law will not affect the ability of Medicaid recipients to obtain medically necessary drugs–and since there is plainly a "possible set of conditions" under which the Maine Rx law does not conflict with Medicaid–there is no "actual conflict" and no preemption under the Supremacy Clause. *See California Coastal Comm'n v. Granite Rock Co.,* 480 U.S. at 509.

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[18] *See Department of Taxation and Finance of New York v. Milhelm Attea Bros., Inc.,* 512 U.S. 61, 69 (1994).

E. The Maine Rx Law Serves a Federal Purpose.

Even though conflict preemption does not require State law to further a federal purpose, the Maine Rx Law does further a Medicaid purpose. The purpose of Medicaid is broad–to enable States to provide medical assistance to "families with dependent children and...aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396. The Maine Rx law furthers this purpose by using Medicaid prior authorization to enable Maine to provide medical assistance to uninsured families and individuals. The Maine Rx law is not addressed to bridge-building or job-training,[19] but to the health care needs of Maine citizens who "are admitted to or treated at hospitals each year because they cannot afford the drugs prescribed for them," who "must enter expensive institutional care settings because they cannot afford their necessary prescription drugs" and who "are threatened by the possibility that when they need medically necessary prescription drugs most they may be unable to

[19] The Solicitor General refers to the "leverag[ing of] its Medicaid program to force a drug manufacturer to fund the State's transportation or education systems," U.S. Br. 25, and Petitioner to subsidization of "food stamps, public housing job training projects, and any number of other public projects that would boost Maine residents' income and thereby potentially keep them off Medicaid." Pet. Br. 25-26. These are entirely hypothetical concerns, since the Maine Rx law does none of these things. But if there is no preemption under the Supremacy Clause, "it is for Congress to rethink the division of regulatory authority in light of its possible exercise by the states to undercut a federal objective. The courts should not assume the role which our system assigns to Congress." *Pacific Gas,* 461 U.S. at 223.

afford their doctor's recommended treatment." Me. Rev. Stat. Ann. c. 603 § A-5(1). The expressly stated purposes of Medicaid and of the Maine Rx law are "common purposes", *Dublino,* 413 U.S. at 421: to ensure that all persons can afford to receive the health care they need.

Limiting Medicaid's purpose to something narrower than Congress's stated purpose is improper.[20] But even viewed narrowly, the Maine Rx law serves a Medicaid purpose. As the court below found, "by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures." 249 F.3d at 76. Specifically, "[w]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible." *Id.* The CMS Director has similarly stated that "making available to financially needy [but not Medicaid-eligible] individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible," is a Medicaid purpose.[21] In his brief, the Solicitor General

[20] Conflict preemption analysis is plainly sensitive to the determined federal "purpose". Petitioner and the Solicitor General ask the Court to find a Medicaid purpose considerably narrower than Congress's expressed purpose; given the breadth and clarity of Congress's language, it is ironic that in the Solicitor General's view, providing affordable health care to uninsured citizens is not a Medicaid purpose, but keeping persons out of the Medicaid program is a legitimate Medicaid purpose. *See, e.g.*, U.S. Br. 35.

[21] Letter of Dennis G. Smith, *supra* note 9. In the Director's view, a State law that uses prior authorization to

agrees that "[a] prescription drug discount for non-Medicaid populations, made possible by encouraging manufacturers to give rebates, could significantly decease the chance that such [lower income persons not meeting Medicaid's eligibility requirements] will become Medicaid-eligible as either categorically or medically needy individuals, and thereby drain the State's scarce Medicaid resources." U.S. Br. 39. Thus, States may "make drugs more affordable to certain non-Medicaid populations by subjecting drugs to prior authorization under Medicaid in order to encourage drug manufacturers to agree to offer prescription drug discounts for those populations." *Id.* at 37-38 (footnote omitted).

There is no real dispute that low-income persons will benefit under the Maine Rx law; the benefits such persons will receive from the Maine program are precisely the same as the benefits they would have received had Maine Rx been limited to such persons. Low income persons represent nearly two-thirds of the nonelderly uninsured, *see* note 2, *supra*; on a facial challenge, it is reasonable to find that the bulk of the Maine Rx benefits will go to low income persons–those with the least means and the greatest need for drugs–and that the primary purpose of the law is also a

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leverage discounts for non-Medicaid persons is a "material change" in State law "and we would therefore expect a State to submit a plan amendment to CMS for review." The Director is careful not to state, however, that Medicaid requires such submission. The fact that a State may apply to CMS for approval, moreover, does not mean that in the absence of such application for approval, State law is preempted. Petitioner has not challenged the Maine Rx law on the ground that no submission to CMS was made–that issue is not before the Court, U.S. Br. 39, n.11–nor would it have standing to do so.

Medicaid purpose.

In his brief, the Solicitor General acknowledges that Medicaid does not preempt State laws employing Medicaid prior authorization to benefit an appropriate non-Medicaid population, U.S. Br. 30, 39, but argues that the Maine Rx law benefits a non-Medicaid group that is too broad.[22] In his view, the Maine Rx law is problematic not because it leverages prior authorization to obtain rebates for non-Medicaid persons–he agrees this is not prohibited by Medicaid, *id.* at 37-39–but because it benefits both persons who may become eligible for Medicaid and others who may not, thus furthering both federal and State purposes.

This is a fine distinction for a constitutional standard. It is not a distinction Congress made when it enacted or amended Medicaid: there is no "clear manifestation of intention," *Dublino*, 413 U.S. at 417, to prevent the States from using prior authorization and rebates to benefit uninsured persons. And it is difficult to see where a requirement that State law *exclusively* further a federal purpose comes from. Conflict preemption asks whether State law is an "obstacle" to a federal purpose. *Pacific Gas.* The Maine Rx law will benefit low-income persons and will benefit Medicaid in precisely the manner the Solicitor General and the CMS Director deem an appropriate Medicaid

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[22] The Solicitor General also argues that the Maine Rx law's statement or purpose does not "reveal any Medicaid objective." Of course, "when considering the purpose of a challenged statute, this Court is not bound by '[t]he name, description or characterization given it by the legislature or the courts of the State,' but will determine for itself the practical impact of the law." *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979) (citation omitted).

purpose: "[a] prescription drug discount for non-Medicaid populations, made possible by encouraging manufacturers to give rebates, could significantly decrease the chance that such persons will become Medicaid-eligible...and thereby drain the State's scarce Medicaid resources." U.S. Br. 39. If State law furthers a federal purpose, it is not an obstacle. There is no preemption.

II. THE MAINE Rx LAW DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE.

The Maine Rx rebates result from the sale, in Maine, of prescription drugs. While most manufacturers sell their drugs to out-of-state middlemen before the drugs are sold in Maine, the Maine Rx law does not regulate or control the prices of those transactions, and the rebates are not based on the prices of those transactions. If the Maine Rx law is barred by the Commerce Clause, "a wide variety of permissible state regulations that may affect the conduct of out-of-state manufacturers," U.S. Cert. Br. 17, including products liability laws, *id.*, and laws regulating insurance and other goods and services sold by out-of-state entities, might also be threatened. For this reason, the Court has found that "the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor*, 477 U. S. 131, 138 (1986).

In the Court's more recent decisions, the dormant Commerce Clause has been employed to prohibit two forms of State conduct.[23] First, a State law may not favor or protect

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[23] In older (primarily common carrier) cases, the dormant Commerce Clause was also invoked to preclude State legislation

in-state over out-of-state commerce. Second, a State law may not control prices or behavior in other States.[24] A law that "has only indirect effects on interstate commerce and regulates evenhandedly," on the other hand, will not be disturbed so long as "the State's interest is legitimate" and the burden on interstate commerce does not "clearly exceed [] the local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

The Maine Rx law does not protect in-state commerce or control behavior in other States and thus is valid under the Commerce Clause.

A. The Maine Rx Law Is Not Improperly Protective.

The "'negative' aspect of the Commerce Clause prohibits economic protectionism–thatis, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *New Energy Co. of Indiana v.*

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in areas in which national uniformity was required, at least in the absence of legitimate State interests. *See, e.g., Southern Pac. Co. v. Arizona*, 325 U. S. 761 (1945).

[24] Decisions striking down laws found to be protective include *West Lynn Creamery, Inc. v. Healy*, 512 U. S. 186 (1994), *New Energy Co. of Indiana v. Limbach*, 486 U. S. 269 (1988), and *Bacchus Imports, Ltd. v. Dias*, 468 U. S. 263 (1984). Decisions striking down "extraterritorial" laws include *Healy v. Beer Inst., Inc.*, 491 U. S. 324 (1989), and *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U. S. 573 (1986). Some laws are both protective and extraterritorial. *See, e. g., Baldwin v. G. A. F. Seelig., Inc.*, 294 U. S. 511 (1935).

Limbach, 486 U.S. at 273. It bars laws when "the avowed purpose of the obstruction, as well as its necessary tendency, is to suppress or mitigate the consequences of competition between the states." *Baldwin,* 294 U.S. at 522. In *West Lynn Creamery,* the Court likened such protection to a State tariff–"[t]he paradigmatic example of a law discriminating against interstate commerce is the protective tariff or customs duty." 512 U.S. at 193. The tariff mechanism "handicap[s] out-of-state competitors, thus artificially encouraging in-state production even when the same goods could be produced at lower costs in other states." *Id.*

The Maine Rx Law is not a protective law, and it does not suppress competition. While Petitioner claims "[t]he Maine Rx rebate has an effect similar to that of a duty imposed at the state's border," Pet. Br. 29, the Maine rebate is not intended to and does not protect in-state producers. It does not establish an "economic barrier" or "rampart", *Baldwin*, 294 U.S. at 527, securing domestic competitors from out-of-state competition. The laws in *West Lynn Creamery, Baldwin,* and other dormant Commerce Clause cases would not have existed had the producers all been in-state producers–protection of in-state from out-of-state producers was the necessary purpose and desired effect of these laws. But if all drug manufacturers were located in Maine, the Maine Rx law would still serve its intended purpose and have its intended effect of increasing access to prescription drugs. It does not injure commerce among the states.

Petitioner seeks to bring the Maine Rx law within the ambit of *West Lynn Creamery* by referring to Maine's prescription drug users as "in-state economic interests" benefitted by the Maine Rx law. Pet. Br. 36, 37. But the law in *West Lynn Creamery* was not struck down simply because

a benefit was conferred on in-state persons. The Commerce Clause concern in *West Lynn Creamery* was that the law's "avowed purpose and its undisputed effect are to enable higher cost Massachusetts farmers to compete with lower cost dairy farmers in other States." 512 U.S. at 194. "The pricing order thus allows Massachusetts dairy farmers who produce at higher cost to sell at or below the price charged by lower cost out-of-state producers," *id.* at 194-95, providing "domestic producers an additional tool with which to shore up their competitive position." *Id.* at 197. "[T]he purpose and effect of the pricing order are to divert market share to Massachusetts dairy farmers. This diversion necessarily injures the dairy farmers in neighboring States." *Id.* at 204. The decision in *West Lynn Creamery* was based on impermissible economic protectionism–the discriminatory advantaging of in-state over out-of-state producers.[25]

The "discrimination" addressed by the dormant Commerce Clause is "discriminat[ion] against interstate commerce." *Bacchus Imports, Ltd v. Dias,* 468 U.S. at 268. In *Bacchus,* on which *West Lynn Creamery* relied, the Court stated a "cardinal of rule of Commerce Clause jurisprudence... that '[n]o State, consistent with the Commerce Clause, may

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[25] Petitioner concedes that *West Lynn Creamery* involved protectionism, but argues that this "feature was neither necessary nor dispositive in *West Lynn,*" and points to the Court's "reject[ion of] Massachusetts' argument that its scheme was not discriminatory because the milk dealers who paid the tax did not compete with the dairy farmers who reaped the subsidy." Pet. Br. 38. The Court rejected this argument not because it found protectionism unnecessary, but because protectionism can be implemented in a variety of ways, including a tax on a third party, and competition can be constrained "at any point." 512 U.S. at 202.

"impose a tax which discriminates against interstate commerce... by providing *a direct commercial advantage to local business.*"'" *Id.* (citations omitted; emphasis added). Commerce Clause "discriminatory effect" is predicated on competition: "as long as there is some competition between the locally produced exempt products and non-exempt products from outside the State, there is a discriminatory effect." *Id.* at 271. The law in *Bacchus* "constitute[d] 'economic protectionism' in every sense of the phrase" and "violated the Commerce Clause because it had both the purpose and effect of discriminating in favor of local products." *Id.* at 273. "It has long been the law that States may not '*build up* [their] *domestic commerce* by means of unequal and oppressive burdens upon *the industry and business of other States.*'" *Id.* at 272 (citation omitted; emphasis added). Petitioner's reference to persons needing drugs as "in-state economic interests" is inapposite for purposes of Commerce Clause analysis–these persons are not engaged in commerce, and the reduction in drug prices is not designed to and does not build up domestic commerce at the expense of the industry and business of other States.

The Maine Rx law does not protect in-state commerce. It has no discriminatory purpose or effect and is not barred by the Commerce Clause.

B. The Maine Rx Law Is Not an Extraterritorial Law.

1. Maine Does Not Regulate Transactions That Take Place Outside Its Borders. In determining whether a State law impermissibly regulates transactions outside its borders, "[t]he critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Healy,* 491 U.S. at 336.

The Maine Rx law does not control any out-of-state transaction. Drug manufacturers subject to the Maine Rx law may transact business anywhere they like, with any entity they like and on any terms they like. Maine does not "dictate the terms on which buyers and sellers do business outside the state," nor does it "regulate the terms of transactions in other states." Pet. Br. 27, 28.

If manufacturers agree to pay a rebate, there is no requirement that they alter their out-of-state conduct in any way. If they do not agree, there is similarly no effect on out-of-state conduct. In either case, it does not matter that the "manufacturers and their customers (independent wholesalers and distributors) are located outside Maine," Pet. Br. 29, because the Maine Rx law does not control the out-of-state conduct of any of these entities. *See* U.S. Cert Br.17.

In *Baldwin, Brown-Forman* and *Healy,* relied on by Petitioner, Pet. Br. 28, the State laws set or determined the prices of transactions in other States. The "'practical effect' of the law[s was] to control...prices in other states." *Brown-Forman,* 476 U.S. at 583. The Maine Rx law, by contrast, does not restrict drug manufacturers' ability to price their products in any State. It does not control wholesale prices or place a ceiling on out-of-state prices. Transactions in other States are not affected by or germane to the Maine Rx law–Maine is neither aware of nor concerned with out-of-state sales. Manufacturers are not required to comply with a Maine regulation in order to sell their products in another State. Maine does not control commerce in other States.

2. Maine Rx Rebates Are Not Impermissibly Tied to Out-of-State Prices. The Maine Rx law directs the Commissioner to "negotiate the amount of the rebate" with manufacturers and in the negotiation to "take into consideration the rebate calculated under the Medicaid Rebate

Program." 22 Me.Rev.Stat.Ann § 2681(4). In the negotiation, the Commissioner is to use "best efforts" to obtain a rebate equal to or greater than the Medicaid rebate amount. *Id.*

The State laws in *Brown-Forman* and *Healy* required sellers to set prices within the State that were no higher than the lowest price charged anywhere else in the United States (*Brown-Forman*) or in neighboring States (*Healy*). Once the seller affirmed that it was selling at the lowest price, it could not then lower its price in other States without violating the first State's law (or, in *Brown-Forman,* obtaining the first State's approval), and thus the first State's price effectively set a floor on the prices in other States. It was this "control" of the other States' prices that made the laws' referential prices offensive. *Brown-Forman,* 476 U.S. at 583.

Under the Maine Rx law, rebates are negotiated. When a rebate is provided, there is no requirement that the negotiated rebate be lower than or higher than or the same as a price charged in any other State. The suggestion in Petitioner's brief that lowering its "federal price will directly trigger a larger Maine Rx rebate," Pet. Br. 34, is inconsistent with the Maine Rx law. There is no "direct" relation between the Maine Rx rebate and any other price.

The issue in *Brown-Forman* and *Healy,* moreover, was not simply that a State law referred to a price; the laws tied in-state retail prices to retail prices *in other States. See, e.g., Healy,* 491 U.S. at 338. A State law that referred to a federal price–even one that mandated the matching of a federal price–could not have this effect; a manufacturer selling to the federal government would be required to charge the same price in the State whose law referred to the federal price, but there would be no effect on prices or commerce in other States. Similarly, if the Maine Rx law required the Maine Rx rebate to match exactly the federal Medicaid rebate

in all cases (there is no such requirement), there would be no impact on the price in any other State. The manufacturer would pay the Medicaid rebate in Maine and would be free to charge whatever price it wanted in other States.

Even Petitioner concedes that "[t]he key offensive element of the price affirmation statutes in *Brown-Forman* and *Healy* was their effect on consumers and the competitive market in other states. The sellers in New York and Connecticut were prevented from setting prices in other states based solely on the competitive conditions prevailing there." Pet. Br. 33. The Maine Rx law does not prevent manufacturers from setting their own retail or wholesale prices in other States or selling their drugs for prices lower than the Maine price in other States. Nor does it prevent them from offering a lower price to the federal government.[26] If other states "follow Maine's lead and link in-state rebate demands to the federal Medicaid rebate level," such States would have "best efforts" negotiated rebate provisions like the Maine Rx law, and there would be no effect on prices in other States. There would be no "competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." *Healy,* 491 U.S. at 337. Manufacturers would be free to negotiate (or refuse to negotiate) appropriate rebates, which might or might not be the same as the Medicaid rebate or each other. There would be no inconsistent obligations and no "price gridlock". *Id.* at 340.

The Maine Rx law does not set or limit prices in other

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[26] Even a mandatory rebate provision that required manufacturers to match exactly the Medicaid rebate would probably not affect the manufacturer's ability to offer a lower price to the federal government, but this is not in any event a Commerce Clause problem.

States, and it is not barred by the Commerce Clause.

C. The Maine Rx Law Must Be Sustained Under the Pike Test

The Maine Rx law is not discriminatory in purpose or effect, and the provision of prescription drugs to Maine citizens is an important local public interest. *See, e.g., New Energy Co. of Indiana v. Limbach,* 486 U.S. at 279 ("[c]ertainly the protection of health is a legitimate state goal"). The Maine Rx law is a legitimate State regulation of health and welfare, and it is not barred by the Commerce Clause. *Pike* v. *Bruce Church, Inc.*, 397 U.S. at 142.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HEALTH, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

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BRIEF OF THE NATIONAL CONFERENCE OF STATE LEGISLATURES, COUNCIL OF STATE GOVERNMENTS, NATIONAL LEAGUE OF CITIES, U.S. CONFERENCE OF MAYORS, INTERNATIONAL CITY/COUNTY MANAGEMENT ASSOCIATION, AND NATIONAL ASSOCIATION OF COUNTIES AS *AMICI CURIAE* SUPPORTING RESPONDENTS

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QUESTIONS PRESENTED

1. Whether the Federal Medicaid statute impliedly preempts Maine from using its prior authorization authority to negotiate discounts on behalf of its citizens who lack prescription drug coverage.

2. Whether Maine Rx violates the dormant Commerce Clause.

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INTEREST OF THE *AMICI CURIAE*

Amici are organizations whose members include state, county, and municipal governments and officials throughout the United States.[1] *Amici* have a compelling interest in legal issues that affect state and local governments.

The Maine Legislature enacted the Maine Rx program "to enable the State to act as a pharmacy benefit manager [PBM] in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare." 22 Me. Rev. Stat. Ann. § 2681.1 (Pet. App. 86a). The statute directs Maine's Commissioner of Human Services to negotiate rebate agreements with drug manufacturers, which are used to reduce retail prices for the uninsured, much as private PBMs negotiate with manufacturers on behalf of the insurance plans they represent. *See id.* § 2681.4.

The court of appeals held that Maine Rx's use of Medicaid prior authorization authority does not conflict with the Medicaid statute. The court also held that the program does not violate the dormant commerce clause. Affirmance of these holdings is necessary to preserve the States' authority to create innovative programs to make necessary prescription drugs more affordable to their citizens who lack insurance.

Because of the importance of this issue to *amici* and their members, this brief is submitted to assist the Court in its resolution of the case.

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[1] The parties have consented to the filing of this *amicus* brief and their letters of consent have been filed with the Clerk. This brief was not authored in whole or in part by counsel for a party, and no person or entity other than *amici* or their members made a monetary contribution toward its preparation and submission.

STATEMENT

1. Prescription drugs have become increasingly important in the treatment of illnesses and chronic conditions. From 1997 through 2001, retail spending on prescription drugs increased at annualized rates of 17 to 18 percent, with total spending rising from $78.9 to $154.5 billion. *See* National Institute for Health Care Management, *Prescription Drug Expenditures In 2001: Another Year of Escalating Costs* 2 (2002). Moreover, "[p]rescription drug expenditures are forecast to continue to rise faster than any other medical service sector over the next decade." *Id.* at 3. HHS estimates that by 2008, prescription drug spending will rise to $243 billion dollars. *See* U.S. Department of Health & Human Services, *Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices* 85 (2000) (Table 2-29); *see also* William H. von Oehsen, III, *et al.*, Public Health Institute/Pharmaceuticals & Indigent Care Program, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities* 2 (2001).

For an individual consumer, the average retail price of a prescription drug rose from $45.27 to $49.84 between 2000 and 2001, an increase of more than ten percent. *See Prescription Drug Expenditures*, *supra*, at 8. Among the fifty drugs with the greatest sales (most of which are patent-protected products), the average price of a prescription rose from $65.79 to $71.56, an 8.8 percent increase. *Id.* at 13.

Prices are even higher for most drugs that are recognized as the leaders in their therapeutic class. For example, in 2001 anti-cholesterol drugs such as Lipitor and Zocor had an average price per prescription of $84.96 and $120.82. *Id.* The anti-ulcerants Prilosec and Prevacid had an average price of $143.68 and $133.20. *Id.* The arthritis treatments Celebrex and Vioxx had an average price of $ 97.32 and $ 85.44. *Id.*

While these figures represent average prices, at the retail level there is a great disparity between prices paid by cash

customers and those who either have insurance or are enrolled in Medicaid or other government-assisted programs. This is due in large part to the differences in bargaining power between the purchaser(s) and both retailers and manufacturers.

For example, cash customers who either pay out of their own pocket or have indemnity-type insurance "generally pay the highest prices for drugs because they lack the opportunity, let alone the bargaining power, to negotiate discounts from either the retail pharmacy or the manufacturer." *See Pharmaceutical Discounts*, *supra*, at 4. These customers, who comprise approximately 25 percent of the market, *see id.*, "generally pay at or above . . . the manufacturer's list price," which is also known as the average wholesale price or AWP. *Id.* at i (Executive Summary); *see also Report to the President*, *supra*, at 99 (figure 3-1).

In contrast, the largest portion of the retail drug market (approximately 65%) involves consumers who belong to a plan managed by a pharmacy benefit manager (PBM), whether a private insurance plan, managed care plan, or a self-insured company plan. *See Pharmaceutical Discounts*, *supra*, at 4; *Report to the President*, *supra*, at 99. Because a PBM "manage[s] . . . drug benefit[s] for a large number of individuals," it has substantial bargaining power and "can negotiate discounts . . . from the manufacturer and from the retail pharmacy." *Report to the President*, *supra*, at 103. Accordingly, manufacturer rebates can range from 5 percent to as much as 35 percent on some drugs. *See id.* at 105.

"PBMs that operate under contract to an insurer or self-insured employer are required to pass on most of the rebates" to their customers. *Report to the President*, at 105. Thus, "PBM customers typically pay less than a drug's average manufacturer's price (AMP)—which is about 20 percent below AWP—and [sometimes] as low as 40 percent below AWP." *Pharmaceutical Discounts*, *supra*, at i (Executive

Summary).[2] Thus, the same drug that costs a cash customer $52, will cost a PBM's customers (the consumer and the plan) an estimated $ 30 to $ 44. *See Report to the President*, *supra*, at 98 (Table 3-1); *see also Pharmaceutical Discounts*, *supra*, at 5 (Chart 3).

Those who lack drug coverage and are charged full retail prices are far more likely to forgo filling a prescription. According to an HHS study of the non-Medicare population in 1996, while 70.0 percent of those with coverage filled at least one prescription, only 33.9 percent of those who lacked coverage did so. *See Report to the President*, *supra*, at 45 (Table 2-2). Moreover, the average number of prescriptions filled was 6.8 for those with coverage but only 2.02 for those without. *See id.* Among persons in fair or poor health, those with coverage filled an average of 25.11 and 37.86 prescriptions respectively. *See id.* at 58 (Table 2-11). In contrast, those without coverage in fair or poor health filled an average of 16.80 and 25.80 prescriptions respectively. *See id.*[3]

A 1997 study by the Centers for Disease Control found that among those who lacked health insurance, 35.7 percent of those in fair health and 60.5 percent of those in poor health reported that they had not filled a prescription because of its cost. *See id.* at 80 (Table 2-27). Moreover, even among

[2] The average manufacturer price (AMP) is the price paid by wholesalers to the manufacturer. *See Pharmaceutical Discounts*, at 5. AWP is the manufacturer' suggested list price for the sale by the wholesaler to the retail pharmacy. *Id.* Manufacturers typically sell to wholesalers at "about 20 percent below the list price or AWP," *Report to the President*, *supra*, at 101, and wholesalers frequently sell to retailers at prices below AWP. *See id.* at 4; *see also Pharmaceutical Discounts*, *supra*, at 5.

[3] For persons in good health, there was also a large difference in prescriptions filled. Those with coverage filled an average of 14.59 prescriptions, those without filled an average of 8.09. *See Report to the President*, *supra*, at 58 (Table 2-11).

those with incomes in excess of 400 percent of the federal poverty line, 13.7 percent of those without insurance reported that they did not fill a prescription because of its cost. *See id.*

2. "[T]o reduce prescription drug prices" for its citizens who lack drug coverage, Maine adopted the Maine Rx Program. 22 Me. Rev. Stat. Ann. § 2681 (Pet. App. 86a). Finding "that affordability is critical in providing access to prescription drugs for Maine residents," the Maine Legislature enacted the program "to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare." *Id.* § 2681.1. The statute directs Maine's Commissioner of Human Services to negotiate rebate agreements with drug manufacturers much as private PBMs negotiate with manufacturers on behalf of the insurance plans they represent. *See id.* § 2681.4 (Pet. App. 87a). When a manufacturer does not enter into a rebate agreement, the Maine Rx statute directs that the Department of Human Services "shall impose prior authorization requirements in the Medicaid program . . . as permitted by law, for the dispensing of prescription drugs by those manufacturers." *Id.* § 2681.7 (Pet. App. 90a).[4]

Under the proposed rules of the Maine Rx program, the State's Department of Human Services will review the drugs of non-participating manufacturers to determine "the clinical

[4] Under the federal Medicaid statute, drug manufacturers must, as a condition of coverage of their drugs, agree to provide rebates on drugs purchased by the Department of Veterans Affairs, the Department of Defense, the Coast Guard, the Public Health Service, and the Indian Health Service. *See* 42 U.S.C. § 1396r-8(a)(1) & (6); *see also* 38 U.S.C. § 8126. The federal Medicaid statute further requires that manufacturers, as a condition of coverage, agree to discounts to various health care entities as defined by 42 U.S.C. § 256b(a)(4). *See* 42 U.S.C. § 1396r-8(a)(1) & (5).

appropriateness of prior authorization for those drugs under the Medicaid Program." J.A. 320. The final determination will be made, however, by the State's Medicaid Drug Utilization Review Committee, a board comprised of licensed physicians and pharmacists, which must make its decision "in accordance with federal and state law." *See id.*, *see also id.* at 149 (affidavit of Timothy S. Clifford, M.D., at ¶ 9). The regulations further require that "[i]n all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs." *Id.* at 320 (Maine Rx proposed rules). Finally, the State "will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process, regardless of whether the manufacturer[] participates in [the] Maine Rx Program by entering into rebate agreements." *Id.* at 149 (Clifford affidavit at ¶9).

SUMMARY OF ARGUMENT

1. The Maine Rx program's use of Medicaid prior authorization authority does not conflict with the Medicaid statute because it does not burden Medicaid patients and physicians. Maine's rule complies with the requirements of 42 U.S.C. § 1396r-8(d)(1)(A). Maine physicians are very familiar with the prior authorization rule as more than 400 drugs are already subject to Medicaid prior authorization. Moreover, the rule does not unreasonably interfere with physicians' free selection of medications because newer and more expensive patent-protected drugs are not necessarily more cost effective than or therapeutically superior to older medications.

There is no evidence in the record that Maine's use of prior authorization authority will actually harm Medicaid patients. Moreover, the State "will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process, regardless of whether the manufacturer[] participates in [the] Maine Rx Program by entering into rebate agreements." J.A. 149. There is thus no merit to the argument that Maine Rx conflicts with the Medicaid statute because it burdens Medicaid patients.

Contrary to the views of petitioner and the United States, Maine Rx's prior authorization rule serves several Medicaid purposes. First, by making prescription drugs more affordable, more people with serious illnesses and chronic conditions will be able to treat those conditions and avoid becoming disabled and forced to go on Medicaid. Second, by subjecting more drugs to prior authorization, the Medicaid program may realize substantial cost savings as cheaper and equally effective generic drugs are substituted for branded drugs.

There is no merit to the contention that Maine's use of Medicaid prior authorization authority to [illegible]iate discounts for a non-Medicaid population violates [illegible]ute. Not only is there no such limitation in the statutory text, the United States uses its Medicaid spending to leverage discounts for a variety of federal agencies and programs that are not related to Medicaid. The sanction the Federal Government imposes when a drug manufacturer refuses to provide discounts for non-Medicaid programs is denying coverage for its drug under Medicaid. This is a far more draconian act for both patients and drug companies than Maine's prior authorization rule, which assures Medicaid patients that they will receive all medically necessary drugs regardless of whether their manufacturers participate in Maine Rx.

2. Maine Rx does not violate the dormant Commerce Clause. Maine Rx neither regulates extraterritorially nor discriminates against interstate commerce.

The extraterritoriality doctrine turns not on the location of the state law's effects, but on the location of the activity that the state law regulates or controls. A state law is unconstitutional if it applies to "commerce that takes place wholly outside the State's borders," *Edgar v. MITE Corp.*, 457 U.S.

624, 642 (1982), even if the law also nominally applies to in-state conduct. But a state law does not violate the dormant Commerce Clause simply because it both regulates in-state economic activity and affects commercial activity outside the State. Numerous important areas of state regulation, such as environmental protection or product liability law, impose additional costs on out-of-state commercial activity but are not thereby rendered unconstitutional.

Maine Rx does not violate the extraterritoriality doctrine because it does not regulate or control out-of-state activity; the program's rebates are based on the retail sale of prescription drugs at Maine pharmacies. Moreover, Maine Rx does not control the conduct of pharmaceutical manufacturers in other States; manufacturers remain free to sell their products at whatever price they can obtain. Nor does Maine Rx impermissibly link prescription drug prices in Maine to drug prices elsewhere; unlike the price-tying schemes that this Court has invalidated, Maine's program does not have the practical effect of controlling prices in other States.

Nor does Maine Rx discriminate against interstate commerce. Petitioner does not allege that Maine Rx facially discriminates or that it was adopted for a discriminatory, protectionist purpose. The program neither attempts to benefit in-state economic interests by burdening out-of-state competitors, nor to benefit Maine consumers of prescription drugs at the expense of out-of-state consumers.

The program regulates pharmaceutical manufacturers even-handedly and there is no evidence of an intent to discriminate against interstate commerce. Although the economic burden of the program could fall principally on out-of-state companies, and the benefits might inure largely to certain Maine residents, such a circumstance has never, in itself, invalidated state regulation under the Commerce Clause. *See, e.g., Exxon Corp. v. Governor of Maryland*, 437 U.S. 117 (1978).

ARGUMENT

I. THE FEDERAL MEDICAID STATUTE DOES NOT IMPLIEDLY PREEMPT MAINE FROM USING ITS PRIOR AUTHORIZATION AUTHORITY TO NEGOTIATE DISCOUNTS ON BEHALF OF ITS CITIZENS WHO LACK PRESCRIPTION DRUG COVERAGE

The court of appeals correctly held that the federal Medicaid statute, 42 U.S.C. § 1396 *et seq.*, does not preempt Maine from using its prior authorization authority to seek discounts on behalf of non-Medicaid populations who lack coverage and are thus charged the highest prices for prescription drugs. This Court should reject PhRMA's facial challenge for two reasons. First, PhRMA has failed to show that Maine's use of its prior authorization authority will conflict with Medicaid's purposes. Second, PhRMA's assertion that "Maine is holding Medicaid patients' prescription drug benefits hostage to the state's fundraising efforts on behalf of others outside the Medicaid program" and that "[s]uch leveraging necessarily conflicts with the Medicaid statute," Pet. Br. 14, is refuted by the United States' use of similar methods to obtain discounts from drug manufacturers on behalf of federal agencies and other non-Medicaid programs. *See* 42 U.S.C. § 1396r-8(a)(1), (5), (6). The judgment of the court of appeals should therefore be affirmed.

A. Maine Rx's Use Of Medicaid Prior Authorization Authority Does Not Conflict With Medicaid's Purposes

1. Congressional intent is the key to any determination that state law is preempted by federal law. *See Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 604-05 (1991); *see also Malone v. White Motor Corp.*, 435 U.S. 497 (1978). While Congress's intent to preempt can be either explicit or implicit, in every case the Court starts with the strong presumption

against preemption of the States' historic powers. As the Court has repeatedly stated, federal law will not preempt state law unless that is "'the clear and manifest purpose of Congress.'" *Wisconsin Public Intervenor*, 501 U.S. at 605 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Where, as here, the claim of preemption is that a state law—which is expressly authorized by the plain language of a federal statute—nonetheless conflicts with federal law because it stands as an obstacle to Congress' objectives, *see* Pet. Br. 15, the Court should be especially skeptical.

The Medicaid program is a "cooperative endeavor" between the States and the Federal Government to provide health care to certain categories of "needy" persons. *Harris v. McRae*, 448 U.S. 297, 308 (1980). "The cornerstone" of "this system of 'cooperative federalism,' . . is [a] financial contribution by both the Federal Government and the participating State." *Id.* (quoting *King v. Smith*, 392 U.S. 309, 316 (1968)). While the Medicaid statute requires that a participating State provide certain benefits under their Medicaid plan, the statute "gives the States substantial discretion to choose the proper mix of amount, scope, and duration limits on coverage" of health care. *Alexander v. Choate*, 469 U.S. 287, 303 (1985). This discretion includes whether and to what extent to provide coverage for outpatient prescription drugs. *See id.*; *see also* 42 U.S.C. § 1396d(a)(12); *id.* § 1396a(a)(54)(A). A State plan must "provide such safeguards as may be necessary to assure that . . . [covered] care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients." 42 U.S.C. § 1396a(a)(19).

2. The starting point in preemption analysis is "the language employed by Congress and the assumption that the ordinary meaning of that language expresses the legislative purpose." *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 740 (1985) (internal quotation and citation omitted). The relevant section of the Medicaid statute

expressly provides that "[a] State may subject to prior authorization *any covered outpatient drug*." 42 U.S.C. § 1396r-8(d)(1)(A) (emphasis added). Congress has imposed only two limitations on a state prior authorization program: 1) the program must "provide [a] response by telephone or other telecommunications device within 24 hours of a request for prior authorization," and 2) the program must "provide[] for the dispensing of at least [a] 72-hour supply of a covered outpatient prescription drug in an emergency situation." *Id.* § 1396r-8(d)(5). Maine's prior authorization program complies with these procedural safeguards. *See* Pet. App. 288a-91a. Indeed, Maine goes even further to protect Medicaid beneficiaries by authorizing a 96-hour emergency supply and by allowing pharmacists to override a prior authorization requirement and issue a one time 34-day supply of a drug. *See* Mainecare Benefits Manual § 80.07-3E.

Petitioner acknowledges that "the Medicaid statute does not expressly bar states from co-opting [*sic*] Medicaid prior authorization authority for non-Medicaid purposes." Pet. Br. 24. Notwithstanding the statute's plain and unambiguous meaning, petitioner asserts that the Maine program conflicts with the federal program because it "burdens . . . Medicaid patients, doctors, and drug company sales" and that this "is sufficient on its face to make out PhRMA's preemption case." *Id.* at 17. None of these alleged burdens establishes that the Maine programs conflicts with the objectives of Medicaid.

First, nothing in the Medicaid statute suggests that one of the Act's purposes is to protect the market share of individual drug manufacturers. Although Maine's use of prior authorization may result in manufacturers who do not participate in Maine Rx losing market share with respect to certain drugs purchased by Medicaid, their loss will become the gain of other manufacturers who participate in Medicaid. *See* 42 U.S.C. § 1396r-8(a)(1) (limiting Medicaid payment for outpatient drugs to those of manufacturers who enter into rebate agreements with the Federal Government). Moreover, as the

affidavit of Dr. Clifford indicates, where a single-source drug "fulfills a unique therapeutic function," it will not be subject to prior authorization regardless of whether the manufacturer participates in Maine Rx. J.A. 149 (Clifford affidavit at ¶ 9).

Second, the prior authorization rule does not unreasonably burden physicians. Prior authorization rules are a common feature of both public and private health care benefit plans with which physicians are very familiar. *See, e.g., Rush Prudential HMO, Inc. v. Moran*, 122 S.Ct. 2151, 2156 (2002); *see also* J.A. 149 (Clifford affidavit at ¶ 11). Indeed, the Medicaid programs of thirty-five States and the District of Columbia impose prior authorization requirements for prescription drugs. Renee Schwalberg *et al.*, Kaiser Commission on Medicaid and the Uninsured, *Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights* 6 (2001).

Moreover, independent of the Maine Rx program, Maine has imposed prior authorization on more than 400 different drugs and dosages that are covered by Medicaid.[5] *See* Maine Medicaid Prior Authorization List, http://www.ghsinc.com/Japps/upload/PA_List_10.01.02xls/ (visited October 2, 2002). In addition to internet posting of the prior authorization list, the State mails the list to prescribers "at least quarterly." Mainecare Benefits Manual, Ch. II, § 80.05-3I. Physicians who treat Maine Medicaid patients can thus readily determine whether a drug is subject to prior authorization. Furthermore, Maine has initiated a program under which primary care "[p]roviders who have consistently prescribed in a cost effective manner have been offered exemptions in various [prior

[5] Of the top fifty drugs by retail sales volume in 2001, thirty-five are on the Maine Medicaid program's prior authorization list. *Compare Prescription Drug Expenditures In 2001, supra*, at 13 (Table 3), with Maine Medicaid Prior Authorization List. Of the fifteen top-selling drugs that are not on Maine's current prior authorization list, four of the drugs are generics, three are antibiotics, and three are hormones.

authorization drug] categories." Maine Department of Human Services, *Pharmacy Update* 2 (Fall 2001). Petitioners have thus failed to show that the Maine Rx prior authorization rule is so burdensome to physicians that it violates the Medicaid statute's goal of providing care and services "in a manner consistent with simplicity of administration." 42 U.S.C. § 1396a(a)(19).

Petitioner further contends that "[t]he prior authorization process interferes with the physician's free selection of medications to treat his or her Medicaid patient, forcing the physician to choose between a first-choice drug that requires prior authorization and a second-choice, possibly less effective, drug that does not." Pet. Br. 15. This speculative hypothesis does not establish that the State's use of prior authorization conflicts with the Medicaid program's goals. Frequently, a "second-choice" drug will produce favorable results in a patient and at a far lower price.[6]

Indeed, as a leading health-care economist explains, there is "a growing stream of new, 'me-too' medications . . . that typically cost twice or three times as much as the drugs they replace. And neither the medical profession nor insurers have

[6] Petitioners do not define the terms "first-choice" and "second-choice" drug. *Amici* note, however, that many drugs that are considered state-of-the-art have lost or will soon lose patent protection. *See* Milt Freudenheim, *Ruling Backs Some Patents on a Leading Ulcer Drug*, N.Y. Times, Oct. 12, 2002, at C14 (noting holding of federal district court that generic version of Prilosec made by Schwarz Pharma did not infringe Astra Zeneca's patents and that "Astra Zeneca is trying to persuade doctors to switch patients from Prilosec to a similar successor drug, Nexium"). For example, a physician treating depression can prescribe either Prozac or its generic equivalent—fluoxentine. While petitioner would likely deem Prozac to be a "first-choice" drug—indeed, it is still considered state of the art—fluoxentine is far cheaper and is therapeutically equivalent to Prozac. Petitioner's terms do not explain whether the generic competitors to leading branded drugs are first-choice or second-choice therapies.

shown much interest in finding out if the higher-priced drugs offer commensurately superior benefits." Uwe E. Reinhardt, *How to Lower the Cost of Drugs*, N.Y. Times, Jan. 3, 2001, at A17; *see also* Stephen S. Hall, *The Claritin Effect: Prescription for Profit*, N.Y. Times Magazine, Mar. 11, 2001, at 40, 42 ("Studies sponsored by drug companies tend to show an advantage for the company's own products."). Moreover, a "first-choice" drug may have a side-effect risk profile that is unsuitable for a particular patient or be contra-indicated because of the patient's condition or other drugs being taken by a patient. *See* J.A. 150 (Clifford affidavit ¶ 12).

Finally, and most importantly, neither petitioner nor the United States has shown that Maine's rule will be enforced in a manner that unreasonably burdens Medicaid patients or that it lacks the "safeguards . . . necessary to assure" that prescription drugs will be made available in "a manner consistent with 'the best interests of [Medicaid] recipients.'" U.S. Br. 19 (quoting 42 U.S.C. § 1396a(a)(19)); *see also* Pet. Br. 17. Petitioner's argument that Medicaid patients will be denied drugs prescribed by their doctors and "find themselves . . . without the means to navigate the prior authorization bureaucracy," *id.*, incorrectly assumes that neither physicians nor pharmacists will assist their patients. Moreover, Maine expressly authorizes a pharmacist "to provide a 96-hour supply" of a covered drug in an emergency, Mainecare Benefits Manual, § 80.07-3D, and "a one-time 34-day supply of the prescribed drug" where the "prescriber fails to submit" the form for requesting authorization. *Id.* § 80.07-3E.

Petitioner further contends that Medicaid patients "may be put through trial-and-error routines on second-choice drugs in order to prove that they need a drug subject to prior authorization" and suggests that this unreasonably risks the health of Medicaid patients. Pet. Br. 17. But even "first-choice" drugs may not be effective in a particular patient and may result in trial-and-error treatment. *See* Hall, *The*

Claritin Effect, *supra*, at 40-42 (noting opinion of two allergy specialists, one of whom believed Claritin was effective in 50 to 55 percent of patients, the other believing that 30 to 40 percent of patients who tried drug benefited). Moreover, a "first-choice" drug might nonetheless cause adverse side effects in a patient.[7] *See, e.g.*, *Physicians' Desk Reference* 2221 (56th ed. 2002) (noting that anti-cholesterol drug "Zocor is contraindicated during pregnancy and in nursing mothers" as well as for patients with "active liver disease" and may cause myopathy); *id.* at 2754 (Table 2) (reporting side effects experienced by patients taking Zoloft in clinical trials which included nausea by 27 percent, diarrhea by 21 percent, insomnia by 22 percent, somnolence by 14 percent, and dizziness by 12 percent).

Finally, state Medicaid plans have long imposed prior authorization requirements on their coverage of prescription drugs and these rules have undoubtedly been applied to numerous Medicaid patients. *See* U.S. Br. 14-15, 18. Nonetheless, petitioner has failed to produce any evidence of actual harm to patients and expressly declined to do so.[8] *See* Pet.

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[7] It is estimated that between 25 to 60 percent of all prescriptions are for non-FDA approved or "off-label uses." James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L. J. 71, 80 (1998). While such use is commonplace and accepted in the medical community, "[e]xamples of off-label uses that have serious medical risks abound," such as the recalled diet drug Fen/phen. *Id.* at 72 n.6 (citing 62 Fed. Reg. 64,080-81). Prior authorization can protect patient safety by ensuring that a prescription for an off-label use is medically appropriate and supported by medical research.

[8] In its lodging, petitioner included a newspaper article relating the story of a Medicaid patient who suffered side effects when taken off of Prilosec because of the State's decision to subject that drug to prior authorization. *See* Pet. Lodging at 20. The factual allegations therein are neither part of the record nor judicially noticeable. *See* Fed. R. Evid. 201(b).

Br. 17. There is thus no merit to the argument that Maine Rx conflicts with the Medicaid statute because it burdens Medicaid patients, physicians, and drug companies.

B. The Maine Rx Prior Authorization Rule Serves Medicaid-Related Goals

The United States and petitioner argue that Maine Rx's use of Medicaid prior authorization authority to seek discounts for the uninsured violates the federal statute because it does not serve a Medicaid-related purpose. *See* Pet. Br. 18-19, 24-26; U.S. Br. 18-22. While acknowledging "[a] State's broad power to subject drugs to a prior authorization requirement," the United States asserts that "the Act contains a further limitation that a State will not use Medicaid's prior authorization provisions in order to further goals unrelated to the Medicaid program." U.S. Br. 18. The Court should reject these arguments, which erroneously assume that Maine's use of prior authorization does not serve Medicaid-related goals. As explained below, Maine's broader use of prior authorization advances Medicaid goals in several ways. Moreover, these arguments ignore that the United States uses its Medicaid spending to leverage discounts for non-Medicaid participants in other federal programs.

First, because Maine Rx will increase access to medicines that prevent, ameliorate or cure disabling illnesses and chronic conditions, fewer members of the State's non-Medicaid population will suffer disabling medical conditions that result in the loss of income and force them onto Medicaid. As the court of appeals recognized, "[w]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible." Pet. App. 13a.

Indeed, petitioner and its members have repeatedly touted the cost savings of their products compared with surgical procedures and hospitalization. For example, one of petitioner's publications notes that "[t]he annual cost of drug therapy [for schizophrenia] was $4,500, compared to more than $73,000 for treatment in a state mental hospital." PhRMA, *The Value of Medicines* 17 (2002); *see also id.* at 14 ("A single hip fracture costs an estimated $41,000, while treatment with a leading hormone replacement medicine that has been shown to prevent osteoporosis costs $730 annually."); *id.* at 19 ("The lifetime cost of a stroke exceeds $100,000 per patient, while the average annual cost of treatment with a blood-thinning drug, including monitoring, is $1,025.").[9]

Unfortunately, "[t]he financial effects of heart attacks and strokes, progressively worsening asthma, or cancer only may begin with medical bills. Such medical problems may leave a wage earner with a sharply reduced or nonexistent earning capacity." *See generally* Melissa B. Jacoby *et al.*, *Rethinking The Debates Over Health Care Financing: Evidence From The Bankruptcy Courts*, 76 N.Y.U. L. Rev. 375, 407 (2001). Thus, a major illness or chronic condition can result in economic devastation even for those who earn more than three times the poverty line.[10] *See id.* at 377 (estimating "that

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[9] Petitioner has also asserted that the "[u]se of cholesterol-lowering medicine reduced hospitalizations and the need for bypass surgery and angioplasty." *The Value of Medicines*, *supra*, at 19; *see also* Pfizer, *Pfizer's Lipitor® Showed Significant Benefit In Reducing Heart Attacks And Stroke*, Oct. 10, 2002 (*available at* http://www.pfizer.com/pfizerinc/about/press/lipitor1010.html). The average cost of bypass surgery is $45,000. *See* John Morgan, *Robotics revolutionizing heart bypass*, U.S.A. Today, Feb. 29, 2000 (*available at* http://www.usatoday.com/lief/health/doctor/1hdoc101.htm).

[10] This is the cutoff for participation in the Maine demonstration project, which the Secretary of HHS has approved as "'likely to assist in

more than half a million middle-class families turned to the bankruptcy courts for help following a[n] illness or injury in 1999"). By reducing the number of persons who suffer disabling illnesses and are forced to go on Medicaid, the Maine Rx program will achieve significant cost-savings for the Medicaid program.

Second, Maine's use of its prior authorization authority may well result in additional cost savings for the Medicaid prescription drug program. As a result of Maine Rx, the State will scrutinize more drugs prior to their dispensing. That action will result in substantial cost savings to the Medicaid program as cheaper and equally effective generic drugs are substituted for branded drugs.

Moreover, because doctors' prescribing decisions may be influenced by drug manufacturers' marketing skills rather than by scientific fact, the Medicaid program may realize additional cost savings by substituting older and cheaper drugs for newer "me—too" drugs that offer no therapeutic advantage. Reinhardt, *How to Lower the Cost of Drugs*, *supra*, at 17. *See also* Hall, *The Claritin Effect*, *supra*, at 42

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promoting the objectives' of the Medicaid program." U.S. Br. 21 (quoting 42 U.S.C. § 1315(a)).

Both the United States and petitioner argue that the Maine Rx program should be invalidated because it is open to all Maine residents. *See* U.S. Br. 22 (noting that "Maine Rx . . . targets persons whose income is in excess of 300% of the federal poverty level[,]" and that "[n]o Medicaid-related purpose is served by a state program focusing on that population"); *see also* Pet. Br. 25 ("The Maine Rx program, which is open to all Maine residents rich or poor, is not, and could not pass muster as, a demonstration project."). It is, however, unlikely that large numbers of wealthy or upper middle class individuals will enroll in the Maine Rx program because it is not an insurance plan. While the program results in lower drug prices, enrollees must pay for their drugs out of their own pocket. Wealthy and upper middle class individuals are thus unlikely to enroll in the plan as they are either covered by their employer's plan or can purchase their own insurance.

(noting that company-sponsored studies "serve as marketing tools, providing drug-company salesmen with their best lines"); Melody Petersen, *Merck Is Said To Limit Perks In Marketing To Physicians*, N.Y.Times, Jan. 18, 2002, § C, at 1 (noting drug manufacturers' "common practice" of providing physicians with "free Broadway plays, weekend trips and other gifts"). To the extent that the Maine Rx rule results in the Medicaid program realizing additional cost savings, Medicaid patients will benefit because the State will be able to maintain a higher level of coverage.

The Maine Rx rule thus clearly serves several Medicaid purposes. *See* U.S. Br. 15 ("subject[ing] covered drugs to prior authorization in order to achieve cost savings for the Medicaid program . . . would further Congress's specific intent"). The fact that it also serves another objective by reducing prescription drug prices for Maine's uninsured citizens does not create an impermissible conflict with the federal scheme.

Finally, notwithstanding the absence of any supporting language in the Medicaid statute's text, the United States and petitioner contend that the act's structure and purpose prohibit Maine from using its prior authorization authority to negotiate discounts for a non-Medicaid population. *See* Pet. Br. 24-25; U.S. Br. 19. According to the United States, "Congress presumably did not intend that a State would leverage its Medicaid program to force a drug manufacturer to fund the State's transportation or education systems." *Id.*; *see also* Pet. Br. 14 ("Maine is holding Medicaid patients' prescription drug benefits hostage to the state's fundraising efforts on behalf of others outside the Medicaid program. Such leveraging necessarily conflicts with the Medicaid statute."). Maine does not, however, seek drug discounts to fund non-health related state programs, but rather to lower the price of prescriptions to make them more affordable for those without drug coverage.

Most significantly, the foregoing contention ignores that the United States uses its Medicaid spending to leverage discounts from drug manufacturers for a variety of federal agencies and programs. [11] A number of these programs impose no income limitation (or an income limitation in excess of 300% of the poverty line) on their patients. *See* 42 U.S.C. § 1396r-8(a)(1), (5), (6); *id.* § 256b(a)(4); 38 U.S.C. § 8126. Under these provisions, a drug manufacturer must, as a condition of Medicaid coverage of their drugs, also agree to provide rebates for drugs purchased by the Defense Department, Coast Guard, Public Health Service, Department of Veterans Affairs, and other covered entities under Section 340B of the Public Health Service Act, 42 U.S.C. § 256b.[12]

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[11] The Medicaid program accounts for 11 percent of prescriptions sold at retail pharmacies. *See Report to the President*, *supra*, at 99 (Figure 3-1).

[12] Veterans who are enrolled in the VA's Medical Benefits Package can receive prescriptions for a modest copayment. In fiscal year 2000, "approximately 1.1 million veterans averaged 47 30-day supply prescriptions per year" through the program. Copayments for Medications, 66 Fed. Reg. 36960, 36962 (2001) (codified at 38 C.F.R. § 17.110). While the VA does impose a means test, the test is used solely to determine whether a veteran must pay the $ 7 per prescription copayment. *See id.* at 36961; *see also* 38 C.F.R. § 17.36(b)(7).

Under the Department of Defense's TRICARE program, dependents of active-duty and retired service members, as well as retired members can obtain prescription drugs for limited copayments, which vary depending upon where they fill their prescription. Indeed, if the person fills the prescription at a military treatment facility, there is no copayment for either a generic or branded drug. The program does not employ a means test. *See* Assistant Secretary of Defense (Health Affairs) & TRICARE Mgmt. Activity, *Pharmacy Co-Pays, available at* http://www.tricare.osd.mil/pharmacy/newcopay.cfm.

Similarly, non-Medicaid patients of programs covered by the Section 340B drug pricing program, 42 U.S.C. § 256b(a)(1), can receive prescription drugs "as long as they are patients of the covered entity." Office of Pharmacy Affairs, *Overview and Frequently Asked Questions 340B—Drug Pricing Program* 3 (available at http://bphc.hrsa.gov/opa/faqs.htm).

The Federal Government's policy of denying Medicaid coverage for a manufacturer's drugs is a draconian sanction that is likely to have a far greater impact on a manufacturer's market share than Maine's use of prior authorization. The federal policy also could have far more deleterious consequences for the health of Medicaid patients than Maine's prior authorization rule—Maine's rule assures Medicaid patients that they will receive all medically necessary drugs regardless of whether their manufacturers participate in Maine Rx. *See* J.A. 149 (Clifford affidavit at ¶ 9). That Congress nonetheless imposed this requirement refutes the United States' and petitioner's contention that the structure and purpose of the statute limit a State's authority to use its Medicaid spending to benefit non-Medicaid populations.

As the foregoing demonstrates, the limitation which the United States and petitioner seek to impose on Maine finds no support in Medicaid's statutory text. Nor can it be implied from the statute's structure and purpose. Medicaid is a cooperative federal-state program in which Maine spends substantial sums on its Medicaid prescription drug benefit ($107.5 million in fiscal year 1999). *See* J.A. 182. Simultaneously, Congress uses its Medicaid spending to leverage discounts for unrelated federal health programs. Under these circumstances, the creation of any such limitation on the States' use of Medicaid prior authorization authority should be left to Congress, which can, if it sees fit, explain to state officials why a policy that is valid for the Federal Government is off-limits to the States.

For example, seventeen of the AIDS Drug Assistance Programs authorized by the Ryan White CARE Act have income eligibility limits greater than 300 percent of the federal poverty line; three of the programs have income limits of 500 percent or greater. *See* Health Resources and Services Administration, *AIDS Drug Assistance Programs (ADAPs) Eligibility Criteria* 1-2 (May 2001).

II. MAINE Rx DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE

The Maine Rx program does not violate the dormant Commerce Clause. Although Maine's program might well affect commercial activity occurring in other States, it does not regulate or effectively control out-of-state conduct. Nor does Maine Rx impermissibly link prescription drug prices in Maine to drug prices elsewhere; unlike the price-tying schemes that this Court has previously invalidated, Maine's program does not have the practical effect of controlling prices in other States. Moreover, Maine Rx does not discriminate against interstate commerce. Although the economic burden of the program could fall principally on out-of-state companies, and the benefits might inure largely to certain Maine residents, such a circumstance has never, in itself, invalidated state regulation under the Commerce Clause.[13]

A. Maine Rx Does Not Regulate Extraterritorially

It is well established that a State "has no power to project its legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there." *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935). Thus, a State may not apply its own law to "commerce that takes place wholly outside of the State's borders." *Edgar v. MITE Corp.*, 457 U.S. 624, 642 (1982) (plurality opinion). Nor may a State "directly control[] commerce occurring outside [its] boundaries," even when the regulation nominally applies only to in-state conduct. *Healy v. Beer Institute*, 491 U.S. 324,

[13] Unless figures in Maine deviate substantially from nationwide statistics, Maine Rx will potentially affect the sale of prescription drugs to considerably less than one-third of Maine's residents. Nationwide, 65% of retail drug sales are to consumers enrolled in a prescription drug plan managed by a third-party pharmacy benefit manager who negotiates discounts on prescription drug retail prices. *See* discussion *supra* at 3. Medicaid covers an additional 11% of prescription drug sales nationwide. *See* note 11, *supra*.

336 (1989). As this Court recognized in *Healy*, the "critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Id.*

At the same time, a state law is not unconstitutional simply because it *affects*—even substantially—commercial activity occurring outside the state. *See* Jack L. Goldsmith & Alan O. Sykes, *The Internet and the Dormant Commerce Clause*, 110 Yale L.J. 785, 803 (2001) ("State regulations are routinely upheld despite what is obviously a significant impact on outside actors."); Donald H. Regan, *Siamese Essays: (I) CTS Corp. v. Dynamics Corp. of America and Dormant Commerce Clause Doctrine; (II) Extraterritorial State Legislation*, 85 Mich. L. Rev. 1865, 1874 (1987) ("the mere fact that a statute has extraterritorial effects does not raise an extraterritoriality problem"). Numerous areas of state law—such as environmental protection, product liability, obscenity, and consumer protection, to name a few—plainly impose additional costs on commercial activity taking place in other States. This Court has never suggested that such extraterritorial effects, standing alone, are sufficient to constitute a violation of the dormant Commerce Clause.

Thus, extraterritoriality questions under the Commerce Clause turn not on the location of the state law's effects, but on the location of the activity that the state law regulates or effectively controls. And Maine Rx regulates or controls only activity that occurs within Maine's borders: the retail sale of drugs at Maine pharmacies. A manufacturer that enters a rebate agreement with the State will not be obligated to make any payments under the program unless its drugs are actually sold in Maine.

Petitioner repeatedly asserts that the State is "regulating wholesale sales by manufacturers that take place wholly outside of Maine," Pet. Br. 27, but no consequences whatsoever flow from a manufacturer's out-of-state wholesaling activity. Petitioner's argument confuses the *target* of the

regulation—here, the pharmaceutical manufacturers—with the conduct that the program regulates. Many state laws target out-of-state actors while permissibly regulating only in-state conduct. For example, state tort law imposes liability on wholly out-of-state manufacturers, but the activity being regulated is the use of the manufacturers' products within the State's borders.

State laws are impermissibly extraterritorial only when they regulate or control out-of-state activity. For example, the law at issue in *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986), required liquor distillers and producers to file advance price schedules each month and affirm that they would not sell at lower prices anywhere in the United States. *Id.* at 575–76. The law regulated extraterritorially because, once a distiller or producer had filed its prices with the State, New York law effectively controlled what prices could be charged in other States. *Id.* at 582–83. It regulated the terms of transactions occurring wholly outside New York.

The same was true in *Healy*, which involved a similar price affirmation scheme. *See* 491 U.S. at 326–29. That law prohibited beer distributors from contemporaneously selling their products in Connecticut at prices higher than those they were charging in surrounding States. *Id.* As in *Brown-Forman*, the law had "the undeniable effect of controlling commercial activity occurring wholly outside the boundary of the State," for once the prices had been posted, Connecticut law forbade sales at lower prices in other States. *Id.* at 337.

Maine Rx, in contrast, exerts no such control over out-of-state conduct. First, Maine's program, by its terms, does not directly regulate any conduct occurring outside the State. Second, Maine Rx does not have the "practical effect" of controlling the conduct of pharmaceutical manufacturers in other States. Unlike the laws in *Brown-Forman* and *Healy*, nothing in Maine Rx dictates the terms on which drug

manufacturers must sell their drugs to wholesalers in other States. The manufacturers remain free to sell their products at whatever price they can obtain.[14]

To be sure, Maine's program may well impose additional costs on out-of-state activities (or reduce the profits that those activities generate), and thus *affect* the price terms of commercial transactions occurring in other States. But the same is true of many state laws that have never raised Commerce Clause concerns. For instance, Maine product liability law might substantially increase drug manufacturers' costs of doing business. Indeed, Maine tort law might have a significant impact on the price of the manufacturers' insurance premiums—insurance that they purchase through wholly out-of-state transactions with their carriers. But these extraterritorial effects would not render Maine's product liability law unconstitutional, even if the manufacturers' "only link to the state is that the goods flow through a stream of interstate commerce that the manufacturers do not control and ultimately come to rest on a pharmacy counter in Maine." Pet. Br. 28. Because Maine's tort law would not have the practical effect of controlling out-of-state conduct, it would not violate the Commerce Clause's extraterritoriality principle.[15]

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[14] Petitioner raises the specter of Maine demanding rebates from "any manufacturer of any product located anywhere in the country," such as oil refiners in Texas or semiconductor manufacturers in California. *See* Pet. Br. 30. Such measures would likely be unconstitutional, either because they singled out products for discriminatory reasons, *see Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263 (1984), or because they unduly burdened interstate commerce, *see Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).

[15] Petitioner suggests that Maine Rx "resembles a sales tax," Pet. Br. 31, and is unconstitutional because it fails the "substantial nexus" prong of the four-part test of *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977). *See* Pet. Br. 31–32. The simple response is that if the program's rebate payments are properly characterized as taxes, this case must be dismissed for want of jurisdiction because petitioner sought injunctive relief and has made no showing that Maine does not provide "a plain,

Nor does Maine Rx impermissibly link drug prices in Maine to the prices that drug manufacturers can charge in other States. What rendered the laws in *Brown-Forman* and *Healy* unconstitutional was that, by requiring that the posted prices be the lowest offered by the sellers anywhere, they had the "undeniable effect of *controlling*" prices in other States. *Healy*, 491 U.S. at 337 (emphasis added). Such price-tying schemes plainly project a State's legislation into other States; they make it a violation of State A's laws to sell goods below a certain price in State B.

Maine Rx has no similar effect. True enough, the program directs the commissioner to use his "best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program," 22 Me. Rev. Stat. § 2681.4.B, an amount that is based in part on the prices that the manufacturers charge throughout the country, *see* 42 U.S.C. § 1396r–8(c)(1). But a State's looking to out-of-state prices as a basis for negotiating its own rebates—essentially engaging in a form of market research—is fundamentally different from a state scheme that effectively *controls* prices elsewhere. A manufacturer's rebate agreement under Maine Rx does nothing to constrain that manufacturer's pricing decisions in other States or in the majority of transactions in Maine itself. *See* note 13, *supra*. No aspect of any out-of-state transaction could violate Maine's law.

Again, Maine Rx might affect commercial transactions occurring wholly outside the State. Indeed, Maine's program

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speedy and efficient remedy" in its own courts. 28 U.S.C. § 1341; *see also California v. Grace Brethren Church*, 457 U.S. 393, 408 (1982). Consequently, if Maine Rx actually imposes a sales tax, the district court did not have jurisdiction in the first instance, and this Court lacks jurisdiction as well. *See Franchise Tax Bd. v. Alcan Aluminium Ltd.*, 493 U.S. 331 (1990) (ordering that case be dismissed after concluding it was barred by Tax Injunction Act); *Rosewell v. LaSalle Nat'l Bank*, 450 U.S. 503 (1981) (same).

might "alter[]" the drug manufacturers' "out-of-state pricing calculations," just as petitioner alleges. Pet. Br. 33. But such an effect, in itself, raises no extraterritoriality concerns under the Commerce Clause.

B. Maine Rx Does Not Discriminate Against Interstate Commerce

Petitioner lastly contends that Maine Rx impermissibly discriminates against interstate commerce "because it externalizes the costs and internalizes the benefits of the program." Pet. Br. 35.[16] As an initial matter, it is important to clarify what petitioner is *not* alleging—namely, that Maine Rx facially discriminates against interstate commerce, or that the State adopted the program with a discriminatory, protectionist purpose. Maine Rx regulates pharmaceutical manufacturers evenhandedly, and there is no evidence of an intent to discriminate against interstate commerce. Thus, Maine Rx could violate the Commerce Clause's nondiscrimination principle only if it discriminated against interstate commerce "in practical effect." *See, e.g., Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333 (1977). Petitioner asserts that Maine Rx does so, relying almost exclusively on *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186 (1994). This claim fails for at least three reasons.

First, *West Lynn* involved the quite different circumstance of a state law that was plainly protectionist in its purpose and effect. In *West Lynn*, Massachusetts had adopted a milk pricing order that imposed a tax on all milk dealers in the State, and then used the tax's proceeds exclusively to

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[16] Petitioner's assertion that Maine Rx forces pharmaceutical companies to externalize costs is, at best, premature as there is no evidence in the record that Maine Rx will necessarily lead to lower profits. As long as rebates negotiated under Maine Rx do not force pharmaceutical companies to sell prescription drugs in Maine at a loss, drug company profits from pharmaceutical sales in Maine could in fact increase due to higher demand resulting from lower, but still profitable, prices.

subsidize Massachusetts dairy farmers. *See id.* 190-91. The pricing order thus operated as a tax "effectively imposed only on out-of-state products," permitting "Massachusetts dairy farmers who produce at higher cost to sell at or below the price charged by lower cost out-of-state producers." *Id.* at 194-95. As this Court recognized, the "avowed purpose" and the "undisputed effect" of the order were protectionist: "to enable higher cost Massachusetts dairy farmers to compete with lower cost dairy farmers in other States." *Id.* at 194. The Massachusetts law was therefore unconstitutional.

Maine Rx, in contrast, has no such protectionist purpose or effect. The program attempts neither to "benefit in-state economic interests by burdening out-of-state competitors," *New Energy Co. v. Limbach*, 486 U.S. 269, 273-74 (1988), nor to benefit Maine consumers of prescription drugs at the expense of out-of-state consumers, *cf. Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662 (1981) (invalidating state limit on truck lengths that benefited in-state highway users at the expense of out-of-state highway users). Of course, the program aims to confer the benefit of lower prescription drug prices on those Maine residents who lack collective purchasing power. *See* discussion *supra* at 3-5. But that does not render the program protectionist in purpose or effect.[17]

Second, a state law is not discriminatory merely because the burden of the regulation falls largely (or even exclusively) on out-of-state interests. *See, e.g., Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456 (1981); *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117 (1978). For example, *Exxon* involved a Maryland statute that prohibited any producer or refiner of petroleum products from operating a retail service station in the State. 437 U.S. at 119. Because

[17] It is also significant that the pricing order invalidated in *West Lynn* consisted of both a tax and a subsidy. If the Maine Rx rebates are properly viewed as taxes, then the Court should dismiss the case for lack of jurisdiction under the Tax Injunction Act. *See* note 15 *supra*.

no petroleum producers or refiners were located in Maryland—just as no pharmaceutical manufacturers are located in Maine—the burden of the regulation fell exclusively on out-of-state companies. *Id.* at 125. In addition, 99 percent of the "independent dealers" that were effectively insulated from the regulation were in-state companies. *Id.* at 138 (Blackmun, J., dissenting).

This Court nonetheless concluded that the statute did not discriminate against interstate commerce. *Id.* at 125-26. "The fact that the burden of a state regulation falls on some interstate companies does not, by itself, establish a claim of discrimination against interstate commerce." *Id.* at 126. Instead, what matters is the regulation's impact on interstate markets: "If the effect of a state regulation is to cause local goods to constitute a larger share, and goods with an out-of-state source to constitute a smaller share, of the total sales in the market . . . the regulation may have a discriminatory effect on interstate commerce." *Id.* at 126 n.16. Because the Maryland statute had no such effect, there was no discrimination against interstate commerce. The same is true of Maine Rx. While the burden of the regulation may fall largely on out-of-state pharmaceutical manufacturers, *but see* note 16, *supra*, petitioner has not contended that the program alters the respective market shares of in-state and out-of-state products. Nor *could* petitioner make such a claim, as there are no Maine manufacturers to protect. Maine Rx thus does not discriminate against interstate commerce as this Court has defined the concept.

Finally, petitioner's discrimination claim rests on the type of "cost externalization" analysis that this Court has expressly disavowed in adjudicating dormant Commerce Clause disputes. In *Commonwealth Edison Co. v. Montana*, 453 U.S. 609 (1981), the plaintiffs challenged Montana's coal severance tax, contending that because 90 percent of the coal mined in Montana was consumed outside the State, the tax

imposed its economic burden primarily on out-of-state consumers and thus discriminated against interstate commerce. *Id.* at 617-18. They argued that while Montana residents enjoyed the full benefit of the tax's revenue, almost all of its costs were felt outside the State.

This Court rejected the claim. First, because the tax made no distinction as to where the coal was consumed, there was "no real discrimination in this case; the tax burden [was] borne according to the amount of coal consumed and not according to any distinction between in-state and out-of-state consumers." *Id.* at 619. The same logic applies to Maine Rx. The size of the rebates depends solely on the amount of the drugs sold in Maine by each manufacturer to Maine Rx participants; all pharmaceutical companies are treated even-handedly, regardless of location. More generally, the Court in *Commonwealth Edison* expressed its "misgivings about judging the validity of a state tax" based on a State's alleged "'exportation' of the tax burden out of State." *Id.* at 618. The same misgivings should give the Court pause here.

In short, asserted "cost exportation" by a state regulation, without more, does not violate the Commerce Clause. Indeed, the rule urged by petitioner—that any state law that confers its benefits exclusively on that State's residents but which disproportionately burdens out-of-state economic interests is, for that reason, unconstitutional—could have far-reaching implications, jeopardizing wide areas of traditional state regulation. There is no warrant for such an expansion of this Court's dormant Commerce Clause doctrine.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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